

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Guidelines
for
Physicians
and
Health Care Providers
on
HIV Counseling,
Testing
and Early Treatment

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH



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February 1990



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The Commonwealth of Massachusetts Executive Office of Human Services Department of Public Health 150 Tremont Street

Boston 02111

February 1990

Dear Colleague:

Two developments in the AIDS epidemic prompt the Department of Public Health to issue these updated Guidelines on HIV Counseling, Testing, and Early Treatment. First, the number of cases reported in Massachusetts continues its inexorable rise. As these Guidelines go to press, nearly 3,000 AIDS cases had been reported in the Commonwealth. In addition, we estimate that there are approximately 32,000 additional HIV+ persons in the state. As the epidemic spreads geographically and demographically, more and more of the state's health care providers are coming into contact with HIV-infected individuals, whether they know it or not.

Second, substantial progress has been made in the development of early treatment and prophylactic care for the HIV-infected. While developments with AZT and prophylaxis for *Pneumocystis carinii* pneumonia represent the most dramatic developments, other treatments are in the offing. For the first time there are encouraging **medical** reasons for a person to know his or her HIV antibody status.

Taken together, these developments mean that we have an ever greater need for your assistance in containing and defeating the AIDS epidemic. As in other emergencies, the medical professions are leading the way in this effort. Now, we request your assistance in identifying persons infected with the Human Immunodeficiency Virus and providing them with the care and counseling that will improve their lives and help contain the spread of the epidemic.

Together we can save tens of thousands of lives and millions of dollars. Our joint efforts will ultimately turn the story of the AIDS epidemic from one of fear and missed opportunities to one of courage and ultimate success. I look forward to working with you in this very important task.

Sincerely,

David H. Mulligan Commissioner

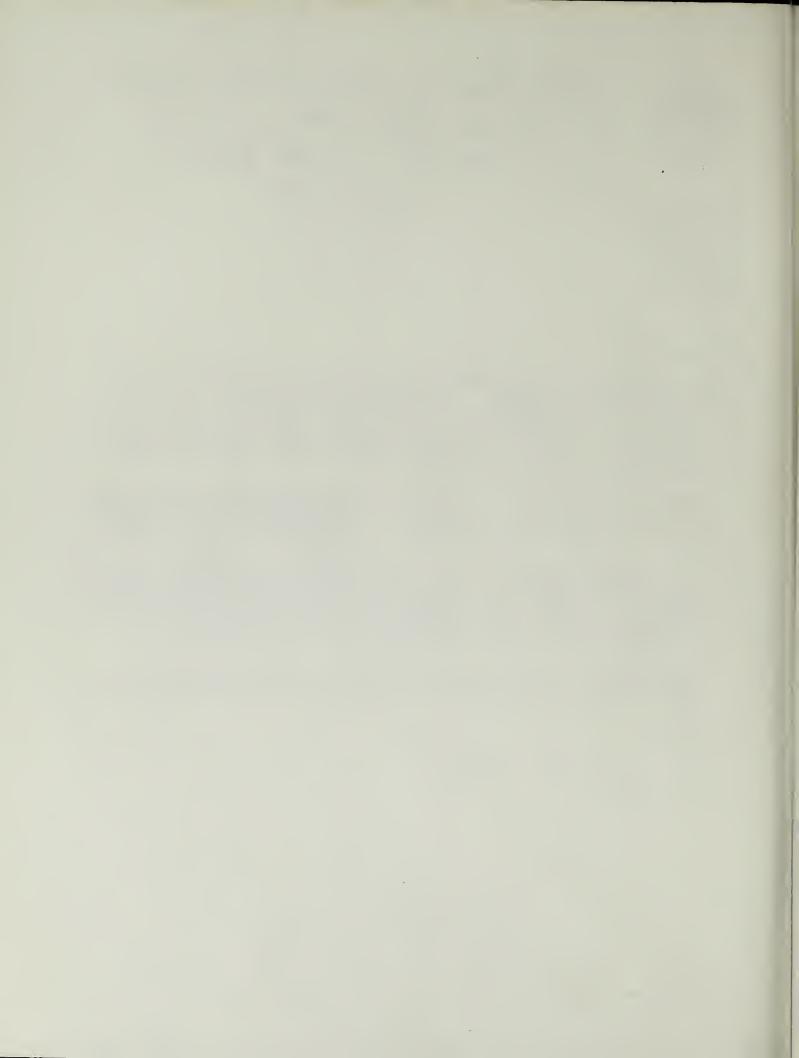
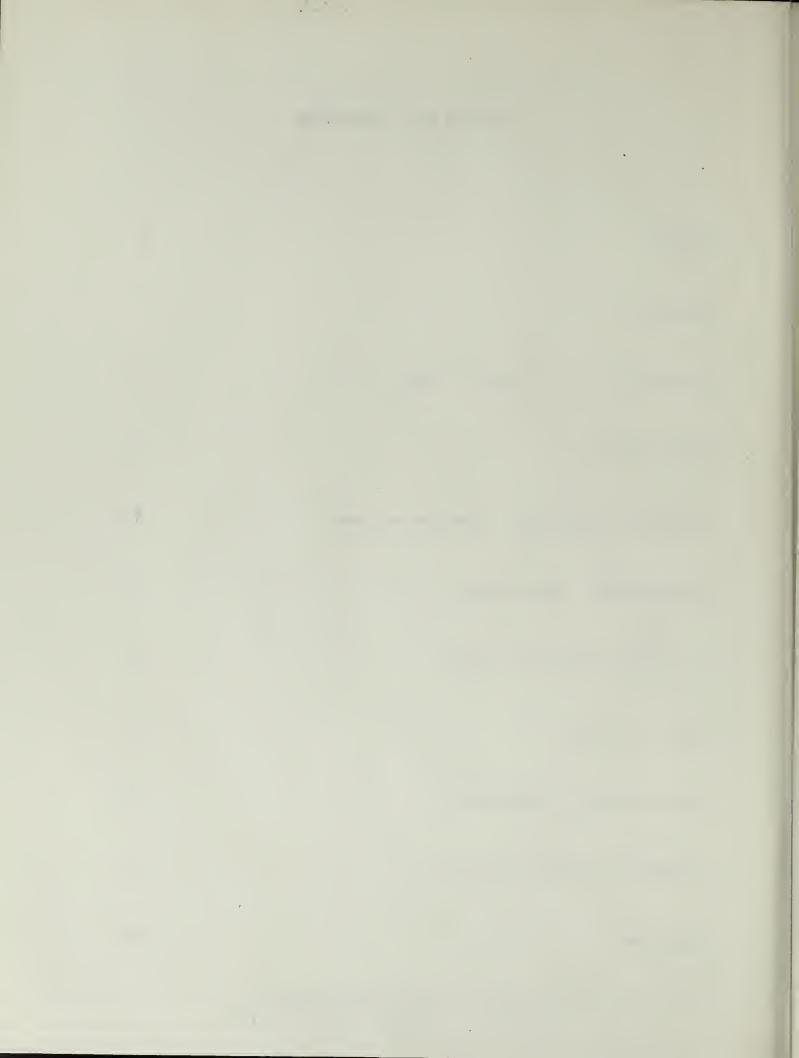


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Abstract

As part of the collaborative efforts of the medical and public health communities in the fight against the HIV epidemic, the Massachusetts Department of Public Health (MDPH) issues these updated Guidelines on HIV Counseling, Testing and Early Treatment. This volume revises previous guidelines on this subject issued by the Department.

Continuing improvement in the efficacy of treatment for HIV disease leads the Department to recommend that physicians consider, as a part of routine medical care, which of their patients may be at risk for HIV infection. Counseling and HIV antibody testing should be offered to all patients at risk for infection. Where appropriate, early treatment should be offered to HIV+ patients.

The Department identifies the following persons whose activities may place them at risk for HIV infection and recommends that they be counseled and tested for the presence of HIV antibodies in accordance with the details of these Guidelines:

- . Men who have had sex with a man.
- . Intravenous drug users who have shared needles or "works."
- . Persons who received blood transfusions or blood products between 1978 and 1985.
- . Sex partners of any of the above.
- . Persons dlagnosed with syphilis, chancroid, genital herpes or tuberculosis.
- . Infants born to or being nursed by women who are HIV+.

It remains the case that testing must be voluntary; written informed consent is required before a person can be tested; pre- and post-test counseling must be provided; and the confidentiality of test results is strictly protected.

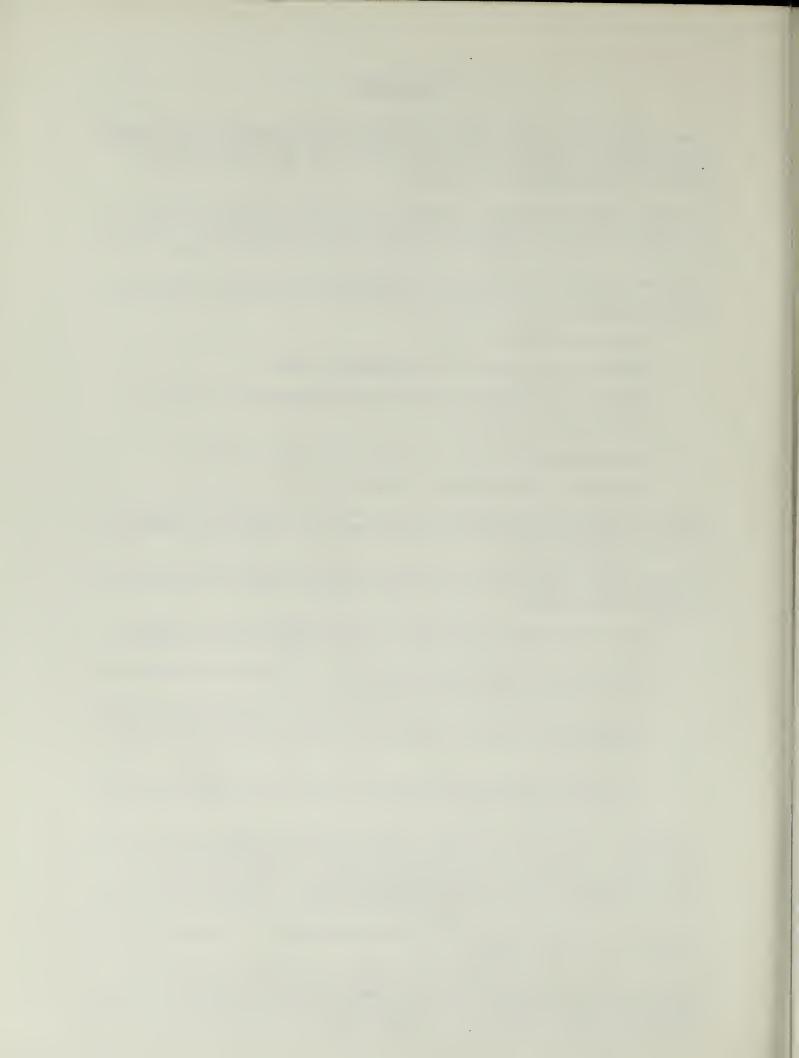
The Department further recommends that physicians who have not already done so should acquaint themselves with early medical treatment and monitoring standards applicable to HIV+ patients. The Department recommends that:

- 1. HIV+ patients should have their T4-cells (T-helper lymphocytes [CD₄ cells]) monitored at least every six months and more frequently as their T4-cells decline below 500/mm³.
- 2. In the absence of contraindications, HIV+ patients should be treated with zidovudine (AZT) when their T4-cell count falls below 500/mm³.
- 3. HIV+ patients with CD₄ cell counts near or below 200/mm³ (or percentage CD₄ cells below 20 percent of total lymphocytes) should receive prophylactic treatment for *Pneumocystis carinii* pneumonia.
- 4. HIV+ women considering pregnancy should be encouraged to defer pregnancy until more is understood about perinatal transmission of HIV infection and the effects of pregnancy on the progression of HIV disease in women.

The Department recommends that physicians integrate HIV and AIDS prevention education into their routine care of patients. Materials designed to assist in this effort have previously been provided as part of required AIDS education in certain patient care settings. This document provides more detailed protocols for incorporation of HIV counseling and testing into general patient care. As in other AIDS prevention activities, counseling about potential effects of HIV testing (both before and after testing) is intended to help reduce risky practices associated with acquiring or transmitting HIV.

This document is also particularly concerned with assuring development of social and psychosocial support systems for the HIV-infected.

The Department restates the **legal prohibitions concerning discrimination** against the HIV-infected or persons perceived to be at risk for HIV infection. Although HIV records, like those related to drug treatment and mental health, are especially protected, the Department encourages physicians (and patients alike) to note that all medical records have long been confidential.



Introduction

This document revises and updates earlier policies of the Massachusetts Department of Public Health (MDPH) regarding testing, counseling and early treatment of persons infected with the Human Immunodeficiency Virus (HIV).

Basic principles of public policy on this subject have not changed:

HIV testing must be voluntary; pre- and post-test counseling must be provided to persons taking the test; informed written consent is required before a person can be tested for HIV antibody or antigen; the confidentiality of HIV test results is strictly protected in Massachusetts; the Commonwealth will provide anonymous testing for persons who desire it.

New in this document is consideration of medical advances in diagnosis and treatment.

Appended to these Guidelines are the following documents which practitioners may find helpful:

- Appendix I. A protocol for taking sexual behavior and drug use histories.
- Appendix II. A protocol for pre-test and post-test counseling.
- Appendix III. An order form for the just published and very comprehensive Clinical Manual for Care of the Adult Patient with HIV Infection published by Boston City Hospital. It is a thorough and informative work which we highly recommend.
- **Appendix IV.** A list of the Testing and Counseling Sites operated by the Commonwealth of Massachusetts and their phone numbers.
- Appendix V. Resources of the Massachusetts Department of Public Health, including useful phone numbers for AIDS related programs.
- Appendix VI. A reprint of a *Project Inform Discussion Paper* advising HIV-infected patients on HIV-related treatment and testing issues. This document is provided to better the physician's understanding of the information available to patients outside the physician's office. It also contains additional useful information.
- Appendix VII. A guide to obtaining drugs (AZT, aerosol pentamidine, alpha interferon) for your patients who may be uninsured or underinsured. Also included is information on how to access aerosol pentamidine for patients whose physicians or clinics do not provide the service in their offices.
- **Appendix VIII.** A copy of the HIV testing consent form used by the Department's testing and counseling sites.
- Appendix IX. An order form for the soon-to-be-published Guide to HIV Counseling and Treatment Among Adolescents.
- Appendix X. Risk factors for HIV infection.
- Appendix XI. Legal protection against discrimination.
- Appendix XII. AIDS information lines in Massachusetts.
- Appendix XIII. Order form for clinical trials information. The MDPH maintains a clinical trials registry and publishes several informative pamphlets on clinical trials.
- Appendix XIV. Excerpts from MMWR Recommendations on Management of Occupational Exposure to Human Immunodeficiency Virus, Including Considerations Regarding Post-exposure Use.

Indications for HIV Counseling and Testing

The Massachusetts Department of Public Health urges all physicians to consider, as an aspect of routine medical care for all patients, which of their patients may be at risk for HIV infection. Counseling and HIV antibody testing should be offered to all patients, particularly those considered to be at risk. Early treatment and medical monitoring should be provided to all HIV+ patients.

Public Health Indications

Counseling, HIV antibody testing, and early treatment play an important role in the prevention of HIV transmission by providing an opportunity to disseminate important public health information. In addition to receiving appropriate medical and mental health care, persons who test HIV+ should be offered counseling on health promotion practices and methods of risk reduction which may benefit their own health as well as prevent transmission of infection.

The HIV antibody test remains an appropriate mechanism for the screening of blood, organ, and semen donors.

The HIV antibody test is not appropriate as a screening device for employment or admission to schools, child day-care, health care or other facilities, and its use for these purposes is prohibited.

Medical Indications

Diagnosis

Antibody testing should be employed by a physician, with patient consent, as an aid to differential diagnosis of potential HIV-associated illness and to determine the most appropriate medical interventions. For example, if tuberculosis, syphilis or herpes is present, HIV testing will identify the possible role of HIV infection and determine if alternatives to standard treatment for these conditions may be appropriate.

Case Finding

HIV antibody testing should also be used for the diagnosis of asymptomatic HIV infection. Early diagnosis of HIV infection permits prophylactic therapy against opportunistic infections and chemotherapy for HIV infection itself. For example, preventive regimens against *Pneumocystis carinii* pneumonia (PCP) are extending short-term patient survival, and zidovudine (AZT) delays progression of the disease.

Immunological staging, such as T-cell testing, has become a standard of practice for monitoring HIV infection and is helpful in determining the degree of immune competence and prognosis.

Risk Assessment

In conducting a risk assessment, physicians should identify potential risk behaviors for each patient (unprotected sexual intercourse, needle sharing, blood transfusion, etc.). Carefully phrased questions focusing on actual behaviors or knowledge of partners' behaviors (e.g., needle sharing) rather than group affiliations (such as intravenous drug users) will better identify risk. Physicians should also consider the hierarchy of risk behaviors and the specificity of risk. For example, an individual who received multiple transfusions in a high prevalence city in 1984 is at higher risk than someone who received a single transfusion in a rural area in 1979.

Geography, while not a risk factor in and of itself, is an issue to be considered in determining risk. In other parts of the world, heterosexual transmission is much more common than in the United States. This fact may be particularly important in the diagnosis and treatment of symptomatic individuals whose risk factors for HIV infection are not obvious.

Current data suggest that occupational risk is very low. However, persons who may have experienced a needle-stick injury or other on-the-job direct exposure (blood-to-blood contact) should be offered counseling, testing, medical monitoring, and where appropriate, early treatment. Clinical trials to establish the efficacy of AZT for prophylaxis after occupational exposure to HIV have been inconclusive. Nevertheless, in some laboratories, standard treatment for needle-stick exposure to infected blood consists of administering AZT on a schedule of 200 mg five times a day beginning within hours after exposure and continuing for four to six weeks. A discussion of the occupational risks and the use of AZT after percutaneous exposure to HIV-infected blood may be found in Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports, January 26, 1990. See Appendix XIV for an excerpt from these recommendations.

Patients who are not at risk for HIV infection or who are at very low risk should nevertheless receive information on how HIV is transmitted and how to avoid risk of infection. Patients who do not disclose risk, but request testing, should receive counseling, testing, and appropriate follow-up.

Risk Assessment in Women

The most common mode of HIV transmission for women in Massachusetts is IV drug use (48%) followed by heterosexual contact with a partner at risk (24%). The vast majority of women with AIDS are in their peak childbearing years with 78% of them being between 13 and 39 years of age. Many of these women were probably infected during their late adolescence. Women with AIDS are more likely to belong to racial or ethnic minority groups, and minority women are more likely than white women to have acquired infection through heterosexual contact.

Risk Assessment in Infants and Children

More than 84% of reported pediatric AIDS cases in Massachusetts are attributed to perinatal transmission. Thus, the risk behaviors of **both** parents should be assessed by the physician. If either parent is in a high-risk category for HIV infection, particular attention should be paid to the child's HIV status. Other considerations should include a child's history of exposure to blood products, transfusion, and sexual abuse.

Who Should be Counseled, Tested, and Monitored?

The MDPH recommends that, after counseling and consent, the following high-risk individuals should be tested:

- . Men who have had sex with a man.
- . Intravenous drug users who have shared needles or "works."
- . Recipients of blood transfusions or blood products between 1978 and 1985.
- . Sex partners of any of the above.
- . Persons diagnosed with syphilis, chancroid, genital herpes, or tuberculosis.
- . Infants born to or being nursed by women who are HIV+.

Notes on Childbearing Concerns

Because infants born to infected parents are at very high risk of infection (current estimates are that approximately one-third of babies born to infected mothers will also be infected), the MDPH recommends that both women and men who have engaged in risk behaviors should consider antibody testing before making reproductive decisions.

An infected woman considering pregnancy should be advised of the risks of pregnancy to her own health, the health of her prospective child, the course of HIV infection in children and the special

needs of children with HIV infection. Although reproductive decisions are the women's choice, the Department recommends that HIV+ women considering pregnancy should defer pregnancy until more is known about perinatal transmission of HIV infection and the effects of pregnancy on the progression of HIV disease in women.

A seropositive pregnant woman must be provided with information on the risks to herself and her child, and she should have access to the full spectrum of health care options in a non-judgmental and non-coercive context.

Notes on IVDUs Entering Drug Detoxification Programs

Intravenous drug users who have shared needles or "works" are at high risk for HIV infection. It may not be appropriate, however, to encourage HIV testing at the same time individuals enter drug detoxification programs or are in early recovery. The Department recommends that individuals entering drug and alcohol treatment services be counseled aggressively on safer sex and other behavior modifications that can prevent the spread of the virus. Except in the face of HIV-related symptoms requiring treatment, high risk IVDUs entering detoxification programs should be tested for HIV infection after completing the initial phases of recovery.

This same caution may apply to alcoholics and drug abusers who are not intravenous drug users when they enter detoxification and other treatment services. Drug treatment programs often advise recovering drug users to delay HIV testing until they are prepared to abstain from drug use and to continue recovery when they learn their HIV status. Individuals diagnosed with an HIV infection are at high risk of resuming drug use and other high risk behaviors that spread HIV infection.

Conditions Which Apply to Testing

The following conditions apply to HIV antibody testing:

Voluntariness

Testing must be voluntary and may be either confidential or anonymous.

Confidentiality

Like other medical records, those related to HIV infection are confidential. Like records related to drug treatment and mental health matters, those dealing with HIV infection should not be shared except under the specific order of a court of competent jurisdiction. The anonymous test sites keep no record whatsoever of the patient's name or other identifying markers.

Chapter 111, section 70(f), of the Massachusetts General Laws provides that a physician, health care provider, or health care facility cannot test for HIV, or disclose test results or even the fact that a person has been tested, without the informed written consent of the person.

Delivering Test Results

Test results should be delivered in person, preferably by the same person who provided pre-test counseling. HiV test results should never be provided over the phone or within earshot of anyone other than the patient and someone of his or her choice.

A Special Note on the Recording of HIV Test Results.

Many patients will be particularly anxious about knowing how the confidentiality of their test results will be protected. As a result of real and perceived problems related to discrimination against the HIV infected, health care providers should seriously consider **not** including HIV test results (or the fact that a test was done) in regular medical files. This procedure is especially true of initial test results of asymptomatic persons, and certainly applies to a patient's self-reporting of HIV infection. In asymptomatic persons, there will be time enough to enter these results on the regular medical

record after the patient has had an opportunity to adjust to the psychological and financial realities of a positive test.

Some practitioners keep HIV results in separate files. Others include this information in an envelope attached to every patient's file; this envelope contains all of a patient's confidential information.

Counseling

Both pre- and post-test counseling must be provided to persons seeking HIV testing (Appendix II). Physicians are strongly encouraged to participate in the ongoing HIV counseling and training sessions offered by the Department of Public Health.

Many of the HIV+ patients who come to the physician's attention may **not** be people tested by their health care provider. They may have learned their antibody status from one of the Commonwealth's testing sites, from the Red Cross or other blood collecting agency, or from an insurer. In cases such as these, the physician should repeat the post-test counseling protocol suggested in Appendix II below.

Informed Consent

Written informed consent is required before HIV testing is permitted in Massachusetts. The consent form must be signed by the person to be tested or by the parent or other person having the capacity to consent to medical care. At MDPH Anonymous Testing Sites, the written consent can be obtained without an identifying signature. All consent forms must include the following information:

- . An explanation of the test, its purpose, and the meaning of the results.
- . An explanation of the testing procedures that will be followed, as well as the information that the test is voluntary, that consent may be withdrawn at any time, and that anonymous testing is available.
- . An explanation of confidentiality protection and allowed disclosures.

(See Appendix VIII for the consent form used by MDPH.)

Pre-Test and Post-Test Counseling

Physicians traditionally counsel patients on a variety of topics; the MDPH recommends that HIV/AIDS counseling be incorporated into the physician's established pattern.

Pre-Test Counseling

Before the consent form is signed, pre-test counseling must be provided.

The physician should assess the patient's understanding of the test and its implications, and his or her ability to deal with the results and benefits from the information. If there are emotional contraindications to testing a patient, counseling should nevertheless be provided on how to reduce the risk of HIV transmission.

It is important to note that prevention efforts are strengthened when an individual has exercised choice and personal responsibility in seeking counseling and testing.

Because patients who receive a positive HIV test often cannot fully comprehend new information at the time of receiving test results, and because some patients may not return to get their test results, good counseling practice suggests covering the following information in the pre-test session:

1. Explain the nature of AIDS and its related illnesses.

- 2. Explain the advantages of knowing one's antibody status in terms of medical management of HIV infection and other conditions.
- 3. Explain which behaviors put one at risk for HIV infection.
- 4. Ascertain the patient's understanding of how he or she can reduce the risk of infection, including the use of condoms.
- 5. Try to understand what, if anything, prevents the adoption of these risk-reduction practices.
- 6. Explain what an HIV antibody test result means.
- 7. Learn what the patient expects his/her test results to be.
- 8. Ask how the patient plans to change his/her behavior.
- 9. How will the patient cope with psychosocial ramifications of a positive test result? Does the patient have health insurance? Should he/she obtain health insurance before being tested?
- 10. If positive, how will the patient tell his or her partners?
- 11. Discuss the importance of partner notification and the availability of the Department of Public Health to help with this task.
- 12. Discuss the possibilities for discrimination that may result from disclosure of a patient's antibody status.
- 13. Finally, your patient should be encouraged to identify:
 - a. one person who knows the patient is being tested.
 - b. one person with whom he/she can discuss the test.
 - c. what he/she plans to do in the 24 hours immediately following receipt of the test result.

Post-Test Counseling

Post-test counseling should always be provided, regardless of the test result. It is an opportunity for the physician to emphasize the importance of risk-reduction practices (such as the use of condoms) to both seropositive and seronegative patients.

For persons who test positive, post-test counseling offers the patient the opportunity to express his or her feelings and concerns, and permits the provider to clarify the implications for the patient's health and to plan for medical follow-up and management.

Post-test counseling for HIV+ individuals should cover:

- 1. Information on available medical treatment and counseling services.
- 2. Development of a comprehensive care plan for the patient.
- 3. Coping with emotional consequences of learning results, including development of a social support plan.
- 4. Behavior change to prevent transmission, including how to use condoms and, where appropriate, how to enter drug/alcohol treatment programs.
- 5. Discrimination problems that could be caused by disclosure of antibody status. (In general, patients should be encouraged to share positive test results only with their closest intimates and to wait before telling others. Discussing disclosure with professional or peer support group/systems is helpful in making these decisions.)
- 6. Need to notify partners.

Partner Notification

Notification strategies available to HIV+ patients include the following:

- . The patient notifies partner(s) without specific assistance by the physician.
- . The patient notifies partner(s) after receiving specific counseling and assistance from the physician.
- . The physician requests the assistance of a public health officer by calling (617) 522-3700, x403.

Medical Assessment and Treatment

The following medical services have clear public health implications, and should be provided to all HIV+ individuals:

- . Syphilis serology
- . Mantoux tuberculin skin test; chest x-ray
- . Hepatitis screen
- . Family planning or pregnancy management, where appropriate
- . Pap smear
- . Pneumococcal (pneumovax) vaccine
- . Annual inactivated influenza vaccine.

A Special Note on T4-Cell Monitoring

Monitoring a patient's T4-cell (CD₄ lymphocytes) counts, percentages, and ratios of T4/T8 has become the standard mechanism for staging the progress of HIV disease. (See Appendix III.) It should be noted here, however, that test results are somewhat variable from lab to lab. In addition, the number of observable CD₄ cells in an individual patient tends to vary diurnally. As a general rule, therefore, treatment should not be undertaken on the basis of a single T4-cell reading but should be based on an established trend line or otherwise confirmed reading.

Treatment Strategies

A variety of diagnostic, therapeutic, and prophylactic measures for medical care of HIV+ individuals are available. Developing therapies and immunological monitoring of CD₄ T-Cells (and other measures of immune function) play an increasingly important role in patient management.

The federal Centers for Disease Control and the Massachusetts Department of Public Health recommend the following measures for PCP prophylaxis:

- 1. Unless contraindicated, prophylaxis for *Pneumocystis carinii* pneumonia (PCP) is recommended for all HIV infected persons with:
 - a. history of a previous episode of PCP, or
 - b. total CD₄ count below 200/mm³, or
 - c. CD, count below 20% of total lymphocytes.
- Monitoring of total or percentage of CD₄ counts at least every six months is recommended for all HIV infected persons. Quarterly monitoring of CD₄ counts is appropriate for all HIV+ persons with CD₄ counts below 200, and may be indicated more frequently in the presence of active symptomatology.

- 3. Regimens recommended for PCP prophylaxis include:
 - a. oral trimethoprim-sulfamethoxazole (TMP-SMX) 160 mg TMP and 800 mg SMX twice daily with 5 mg leucoverin once daily, or
 - b. aerosolized pentamidine (AP), 300 mg every four weeks via the Respirgard II jet nebulizer.

For additional information, contraindications and precautions for health care workers, see MMWR Guidelines for Prophylaxis Against Pneumocystis carinii pneumonia (PCP) for Persons Infected with Human Immunodeficiency Virus, June 16, 1989.

Furthermore, if you have a patient(s) who should be receiving aerosol pentamidine but this service is not available in your office or clinic, you should see Appendix VII of this document for advice on how arrangements may be made for this service.

Zidovudine (AZT) can significantly decrease the rate of disease progression in HIV+ people whose CD₄ cell count is below 500. This finding is true for persons with or without HIV-related symptoms. For patients who are asymptomatic, a dosage of 100 mg 5 times a day can be employed with very infrequent adverse reactions. For patients who have had PCP, the FDA now recommends a regimen of 200 mg 6 times a day for 30 days followed by 100 mg 6 times a day thereafter.

Currently, there are no recommendations for prophylactic treatment for pregnant women or children under 13 years of age. However, several clinical trials are in progress.

Follow-Up

To assure a high standard of care, it is important to evaluate seropositive patients medically and psychologically and to develop and implement a treatment plan and preventive strategies either directly or through referral.

A network of medical, psychological, and social support services can be of significant value for the health and well-being of HIV-infected individuals. The MDPH recommends that physicians be familiar with the community resources available to assist the patient with a variety of needs.

A comprehensive compilation of this information should be available through the Boston AIDS Consortium by summer 1990.

Interpreting HIV Antibody Test Results

Reliability

Blood is tested for HIV antibodies by licensed clinical laboratories with the enzyme-linked immunosorbent assay (ELISA); specimens repeatedly reactive with ELISA are tested with a confirmatory Western Blot. Together these tests are sensitive and specific (98% specificity in high-risk groups).

Adults/Children Older Than 15 Months

Positive Result

A positive test for HIV antibody is now considered to be a marker of on-going infection with HIV. Rare false positive reactions continue to be seen, and some infected persons do not develop detectable antibody, especially if recently infected.

A confirmed HIV antibody test is now viewed as an indicator of infectivity (only through blood or sexual fluids), and also indicates a high probability that clinical AIDS will develop over a period ranging from months to years.

Negative Result

A negative result indicates that the individual probably has not been infected with HIV. However, because in a small number of cases it may take several months for antibodies to develop, the result might not be reliable if the individual has engaged in risk behavior within six months of taking the test. Physicians should attempt to assess the patient's last risk contact before scheduling a retest.

Indeterminate Result

An indeterminate result indicates that the result is neither clearly negative nor positive. This result happens routinely with 2 to 3% of tests and may be due to a number of medical factors unrelated to HIV or AIDS. An indeterminate result does not indicate whether the individual is or is not infected with HIV. If the patient wishes to be retested, he or she should be advised to wait at least one month, and should be told that the test might again be indeterminate. If the patient has received two indeterminate results, and wishes to be tested a third time, he or she should wait four months after the last test.

Children Younger Than 15 Months

Positive Result

A positive HIV test result has a different meaning for children under the age of 15 months than it does for children over this age. HIV antibodies detected in the newborn reflect maternal antibody acquired through the placenta and do not necessarily indicate HIV infection in the child.

Current studies indicate that these maternal antibodies may persist up to 15 months after birth. An infant with a positive test result should be retested and reevaluated periodically to determine whether or not he or she is infected.

Negative Result

A negative result generally means the child is not infected with HIV. However, after maternal antibody disappears, an infected baby may test negative for a limited period: it is presumed that these children were infected perinatally, but had delayed production of their own antibody.

Inconclusive Result

Same as for adults.

Test Sites

MDPH Alternative Test Sites provide anonymous testing and counseling at various locations. (See Appendix IV for their locations and phone numbers.)

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Appendix I

Protocol for Taking Sexual Behavior and Drug Use History

The pre-test counseling session must include specific questions on sexual behavior and drug use. The physician should use frank, non-judgmental, open-ended questions in the history-taking to determine whether the patient is at risk for HIV infection. The physician must be careful to avoid using technical jargon and be certain that the patient understands the words being used.

Discussing sexual behavior is difficult for many patients and physicians. The interview style and terminology used should be tailored to suit the comfort and cultural background of the individual patient and physician. Some physicians may adopt an informal style of collecting information on sexual practices over the course of an interview, while others may prefer to collect this information in a more direct fashion. It is important for the physician to keep in mind that the patient's sexual orientation is less important than the specific sexual practices in which he or she engages.

Collection of information may begin with an introductory statement such as, "In order to give you the best care I can, I need to ask some questions about your lifestyle and health-related behaviors." The following is provided as an outline for the type of information that should be gathered:

- . Past history of sexually transmitted disease.
- . Current sexual practices and number of steady/non-steady partners.
- . Past sexual practices and relationship history.
- . History of sexual abuse/sexual assault.
- . Regular sexual partners:
 - . Sex with male prostitute
 - . Sex with female prostitute
 - . Sex with IV drug user
 - . Sex with suspected/confirmed HIV-infected individual.

Specific sexual practices:

- . Penile-vaginal activity (ejaculation, pain, use of condoms)
- . Oral-genital activity (receptive, insertive, use of condoms, semen deposited)
- . Oral-anal activity (receptive, insertive)
- . Anal-genital activity (receptive, insertive, ejaculation, bleeding, douching, use of lubricants, use of condoms, rectal pain)
- . Mutual masturbation.

Discussing drug use with patients can be as difficult as taking a sexual practices history. Stressing the need for complete information in order to provide optimal health care can facilitate matters. The physician may wish to use an introductory comment such as, "Drug use can be an important factor in your health. Therefore, I would like to know if, how often, and how you use the following:"

- . Alcohol
- . Marijuana (pot, grass, etc.)
- . Barbiturates and other sedatives (e.g., downers, reds, black beauties)
- . Amphetamines and other stimulants (e.g., uppers, speed, PCP, meth, ice, crystal)
- . Hallucinogens (e.g., LSD, PCP, mushroom)
- . Cocaine (coke, crack)
- . Heroin
- . Other injected drugs.

Knowledge about non-intravenous drug use can assist the physician in making important recommendations about maintaining health in seropositive and seronegative persons. Physicians should also advise patients that use of psychoactive drugs may make adherence to safer sex guidelines difficult.

A Special Note About Medical Records

As difficult as these issues are, many patients will still feel more at ease discussing their drug use and sexual practice histories with physicians if these histories are not recorded in their medical records. You may wish to offer your patients the option of answering questions regarding these matters without their being permanently recorded.

Appendix II

Protocol for Pre-Test and Post-Test Counseling

In the absence of a cure, our best hope of stemming the HIV epidemic still depends on our ability to educate. Knowledge about the virus, its transmission, an individual's infection status, and about how to maintain one's health are vital. Experience indicates that one of the most effective vehicles for developing this knowledge is HIV counseling. The outline of pre- and post-test counseling presented here is a distillation of the practical experience of physicians and test site counselors.

As indicated earlier, many of the HIV+ patients who come to your attention may **not** be people you have tested. They may have learned their antibody status from one of the Commonwealth's testing sites, from the Red Cross or other blood collecting agency, or from an insurer. In cases such as these, you should repeat the post-test counseling protocol suggested below.

The physician's overall goal in providing HIV counseling and testing is to assure good medical management and to help the patient develop healthy behavioral practices and coping strategies. The specific objectives of HIV counseling sessions are to help the patient to understand:

- . What the virus is and how it is transmitted.
- . The behaviors that have and/or will put him or her at risk for HIV infection.
- . How to use risk-reduction practices and seek help for specific problems that interfere with implementing these practices.
- . What the test results mean and how they are used in medical management.
- . How to plan for the test result, including mobilizing supports and developing a plan for partner notification and medical follow-up so that, whether negative or positive, the result will support disease-control efforts and personal health care.

Counseling Suggestions

Included here are the pre-test and post-test HIV counseling and testing protocols. The importance of the pre-test counseling session cannot be overestimated. This session is where the prevention message is most likely to be absorbed. In the post-test session, the test result (whether negative or positive) may be the only piece of information that the patient can easily take in. We urge physicians to take advantage of the pre-test counseling session to impart information and identify the resources which will enable the patient to cope with the test result and to reduce his or her risk of contracting or transmitting HIV. The pre-test sessions can raise a patient's anxiety level as he or she explores personal risk for HIV infection. Acknowledging and discussing this stress are critical to the counseling process. The post-test counseling session requires the physician to deal with intense feelings, as well as to impart understandable medical information. We hope this protocol will aid you in handling the unique demands of HIV counseling.

Pre-Test Counseling

The following is a 12-step guide to assist you in sharing and gathering information which will help patients consider and understand the value of HIV antibody testing for prevention and medical management. These steps should be completed before a patient signs the required informed consent form and the test is ordered.

SUMMARY: HIV PRE-TEST COUNSELING

Step 1: Engagement

Step 2: Reason for Testing

Step 3: Current Health Assessment

Step 4: Risk Assessment

Step 5: Risk Reduction/Barriers/Referrals

Step 6: Clarifying Meaning of Test

Step 7: Plan for Test Results

Step 8: Plan for Partner Notification

Step 9: Discussion of Confidentiality

Step 10: Summary of Session

Step 11: Arriving at a Decision

Step 12: Completing the Informed Consent

Step 1: Engagement

Put the patient at ease and establish rapport, using methods that you find effective.

Step 2: Reason for Testing

Patient has asked to be tested.

"Why do you want to take the HIV test at this time?" This open-ended question will help you and the patient determine his or her immediate concerns. It helps you assess whether this is a well-thought-out plan to further AIDS prevention and medical management, or an impulsive action. Look for the recent precipitant, such as a symptom, the death of a friend, a news article, pregnancy, or referral from another professional.

Health provider suggests testing.

"We are talking to everyone about AIDS prevention and the usefulness of HIV testing." It is strongly recommended that a sex and drug history to assess risk for HIV be included as a routine part of a medical visit. When risk for HIV and the option of testing is excluded from routine history-taking, patients may mistakenly assume they are "AIDS free." Because so many persons with HIV infection look and feel fine for many years, it is easy for them to avoid thinking about the possibility that they may in fact be infected with the virus. "In light of your history (drug or sexually-transmitted disease) and/or your current symptoms, finding out whether you are infected with HIV is medically indicated." The benefits of testing in relation to early medical intervention and management should be explained.

If the patient resists discussion, it is important to let him or her know that you understand it is difficult to talk, but that you think this discussion is an important step for him or her in health care and maintenance.

Step 3: Current Health Assessment

"Do you believe you have symptoms that might be related to HIV? Do you think you have other infections such as a sexually transmitted disease or TB, or other health concerns?"

Discuss the patient's concerns. Individuals with HIV-related symptoms can proceed with testing, but should be assessed immediately for any HIV-related illness and, if necessary, referred for appropriate medical care.

Step 4: Risk Assessment

Explain why you are asking questions about sensitive areas of your patient's life. "So that I can address your (my) concerns and discuss the usefulness of the HIV-antibody test with you, I would like to ask you a few questions about yourself and your behavior. This way we can explore whether you may be at risk for HIV. After that, I'll review with you the details of the test."

When asking questions about sensitive lifestyle risk factors, continue to reassure the patient that you know it is difficult to talk directly about sexual and drug-use behavior, but that the questions are asked to develop a good risk assessment for this disease, increase accuracy of the patient's self-appraisal, and provide the best possible counseling.

"What specific behaviors or activities have you engaged in that lead you to believe that you might be infected by HIV?" or "What do you know about how AIDS is transmitted and about your own risk for contracting it?"

Clarify any misinformation the patient has about modes of transmission. Identify whether the patient is aware of having engaged in high-risk activities and explore in detail current and past risk behavior(s). Remember to look for multiple risk factors.

As you conduct the risk assessment, you should help the patient understand the cause and effect relationship between specific behavioral practices and risk for acquiring HIV. It will enable you to provide risk-reduction information specific to the patient's own risk activities. This information is critical to encouraging and empowering someone to modify his or her behavior.

Explore whether your patient's self-appraisal of risk for HIV infection is in line with your assessment of that risk. If the perceptions are at odds, identify and discuss what the reasons might be.

People minimize reports of their own risk behavior for many reasons, including fear of intrusion by government authorities, the shame attached to disclosure of or identification with certain behaviors, and spontaneous denial used to reduce fear and anxiety. Talk frankly about these barriers to open the discussion.

Testing should be offered as the most accurate method of ascertaining whether the patient is infected and in need of special medical management.

Reassure the patient about the safety of casual contact. "No, you can't get AIDS unless you had unprotected sex with that person," or "You can play with the baby with AIDS all you want. It's safe."

Step 5: Risk Reduction/Barriers/Referrals

Patients' knowledge of risk-reduction practices vary greatly. By asking, "What are you doing to reduce your risk of getting AIDS?" you can start with the patient's knowledge base and fill in the gaps. Do not assume, however, that the new information you offer will be automatically or immediately accepted.

Encourage the patient to think through what safer sex would be like for him or her. How would sexual behavior have to change? Ask what has been the hardest thing to change. Discuss attitudes and behavior of current partners. Ask the patient to describe in detail his or her last high-risk activity and use the answer to identify barriers to risk reduction and resources available to address them: "It seems that whenever you drink, you don't use condoms...maybe we should talk about how your drinking affects you and your partner's safety." Demonstrate or provide literature that describes proper condom use, and when appropriate, clean-needle use. Give referrals (drug treatment, support groups) to the patient needing further assistance.

Reiterate that the patient should implement these risk reduction guidelines whether or not he or she is tested, in order to prevent future exposure or transmission of the virus.

Step 6: Clarify Meaning of Test

"What would a positive test result mean to you? What would a negative test result mean to you? If tested, do you think you would be positive or negative?"

Encourage the patient to describe in his or her own words what an HIV+ test result means. Clarify and correct misinformation about the significance of test results with particular attention to current understanding of the test's prognostic significance. "The test can tell you whether you've been infected with HIV, the virus that can cause AIDS, and whether you can pass the virus on to others through specific activities," or "It can't tell you if you have AIDS, but it can tell you if you might develop AIDS. Additional tests would help us determine how well your immune system (body's defense system) is working and whether you might benefit from medication at this time." Special

attention should be given to the patient who has unrealistic expectations about test outcome, especially the person who may well test positive but thinks she or he is negative.

Step 7: Plan for Test Results

"What specific changes in your lifestyle, if any, would you make if you tested positive? If you tested negative?"

Help the patient evaluate whether these changes would support or hinder a positive health-maintenance action plan (If I test positive it'll all be over and I'll go on a drug run." or "If I test positive I want to avoid getting pregnant, and if I test negative I'll get pregnant.")

Help the individual anticipate, at a minimum, short-term distress generated by a positive test result. Explore his or her support system and try to identify at least one person - either a friend or a professional - to whom he or she can turn.

If the patient has a history of psychiatric disturbance, assess the risk for relapse. Assess the risk for suicide. Consider psychiatric consultation before testing when a significant risk is present.

Step 8: Plan for Partner Notification

Discuss the importance of notification of sexual and needle-sharing partners if the patient's test result turns out to be positive. Discuss service options available to assist with this task. Assistance with partner notification can be arranged by the physician by calling (617) 522-3700 x410.

Step 9: Discussion of Confidentiality

"What have you heard about how test results could be misused?" A review of confidentiality guidelines is important. Discuss the possibility of discrimination in employment, housing, and insurance based on positive test results if confidentiality is not maintained. Offer the option of either confidential testing, where the test information is included in the patient's chart, or anonymous testing, where the person is identified by number only. Appointments for anonymous testing can be made by calling (617) 522-4090.

Step 10: Summary of Session

Does the patient have an accurate understanding of the test's significance?

Is the patient at risk for self-destructive behavior if found to be HIV+?

Do you believe that the testing will help or hinder the patient's capacity to develop or maintain a health care action plan?

Do you believe the patient is able to follow through on getting medical follow-up and mobilizing social support if HIV+?

Share your assessment with the individual and explore problems and concerns further. Discuss resources and referrals that might assist in resolving these problems. The decision to take the test is the patient's alone.

Step 11: Arriving at a Decision

"Do you think you have enough information to make a decision?" If the answer is no: "What needs clarification? Do you want to make the decision now or give it further thought?" If the answer is yes, make plans for a follow-up session.

Step 12: Completing the Informed Consent

When the patient decides to be tested, complete the paperwork and have blood drawn. Schedule a post-test counseling session to give the test result and provide referrals (i.e., drug treatment) where indicated.

Post-Test Counseling

It can be quite painful to watch as the patient hears the words "HIV positive." Because there is no one right way to handle the post-test session, this guide presents a flexible approach in which the patient is encouraged to take the lead in presenting his or her concerns, and getting answers to questions. The physician should weave into the fabric of the session the major issues discussed in the pre-test session. The following is an 11-step guide to assist you in the process.

SUMMARY: HIV Post-Test Counseling

Step 1: Give Test Result Right Away

Step 2: Allow the Patient to Absorb Information

Step 3: Encourage Patient to Share Initial Reactions

Step 4: Establish Priorities

Step 5: Clarify Meaning of Test Result

Step 6: Develop Medical Follow-Up Plan

Step 7: Review Risk-Reduction Guidelines and Plan

Step 8: Review and Implement Partner Notification Plan

Step 9: Review Confidentiality Issues

Step 10: Mobilize Support Systems

Step 11: Summarize Plans for Referral and Follow-Up

Step 1: Give Test Result Right Away

Begin the session by giving the test result in a straightforward manner without comment. Preceding the result with icebreakers or chitchat only adds to the patient's mounting anxiety in anticipation of getting the test result. It is helpful if you are relaxed and speak in a tone which suggests calm and confidence. The test result must be given in person in order to assess the patient's understanding of it, psychological reactions, likelihood of continuing risk behavior, and need for follow-up care, including psychiatric services.

Step 2: Allow the Patient to Absorb Information

Patients are usually relieved when they hear, "You are HIV-negative." Since most people associate "negative" with bad news, it is important to add some clarifying words. "This means the HIV virus was not detected in your blood. So, unless you engaged in risky behavior in the past six months, it means you probably do not have the AIDS virus." Patients who may continue to show stress are those who have a partner who is infected, someone in the "window period for infection," someone who has lost many friends to AIDS, and someone who is irrationally obsessed with AIDS.

Patients vary in their initial response to hearing that they tested HIV+. Sometimes they flinch as though warding off a blow or blood rushes to their face or drains away. Some patients jump up and race for the door, others stare in disbelief, smile, or start weeping and reach to clutch your hand. Persons providing HIV counseling often worry that the emotion of the moment will overwhelm their professional discipline and leave them ineffective. In an effort to deal with this stress, some pre-empt the patient's reaction by quoting survival statistics, giving medical advice and research protocols--leaving the patient behind to cope with the bad news.

Observe the behavioral reactions for clues about the patient's internal state. Some people need to absorb the news in silence with the physician staying nearby. Others are threatened by silence and need the physician to fill the room with a stabilizing voice or to more actively keep them in the room.

Step 3: Encourage Patient to Share initial Reactions

After allowing time for the patient to react - with tears or silence - encourage the patient to share what is happening inside. Phrases like "What are you feeling right now?" or "What's going on for you?" can help patients put their feelings into words. It is important to listen to all they have to say about how they are feeling. It is not your job right now to reassure them that they are fine and they are not going to die. It is helpful to repeat, literally, the words the patient has used.

If he or she says, "I'm positive - that means I have AIDS and will die," you can say, "What I hear you saying is that you feel that since you have tested positive, you think you have AIDS." A patient might say, "Good, I'm negative. That means my boyfriend is clean." Continue to reach for all of the concerns and beliefs before correcting any misconceptions.

If the patient expresses self-injurious thoughts, or feelings, explore in detail current suicidal thoughts and past suicidal attempts. "What have you thought about doing to yourself or others to get rid of all this pain?" "What are the things that would stop you?" "Have you ever tried to hurt yourself or someone else before?" It is important to note that it is normal for HIV-infected individuals to have suicidal or aggressive thoughts. However, the more concrete the plan, the greater is the current risk, particularly when there is a past history. Seek psychiatric consultation if it is indicated.

Step 4: Establish Priorities

Summarize all of the concerns you have heard. "It seems you have several concerns - telling your lover/partner and family - being around your children - getting home in one piece."

Help the patient start thinking one step, one day at a time, asking, "Which of these issues is of greatest concern?" Reassure the patient that he/she can expect to have many concerns right now because of this new, uncertain, and potentially threatening information. Start to offer correct information.

Step 5: Clarify Meaning of Test Result

Some patients believe that a positive result means imminent death. Some think it can't be true and the lab has made a mistake. Begin with what the patient is telling you the test result means to him or her. You could say, "What I hear you saying is that you feel this means you have AIDS and you are going to die," or "It sounds as though you believe your boyfriend doesn't have the virus because you are seronegative. What information do you have that makes you think that?" Repeat what the patient has said and continue to correct misinformation. "It might be helpful for us to review some of the information we discussed in the pre-test session." Review the difference between asymptomatic infection, AIDS-Related Complex, and AIDS, encouraging the patient to explain how he or she understands this information.

Continue to restate and clarify what the patient presents. For example, "A positive test means the virus is inside of you and that you can pass it to others through specific sexual and needle/blood sharing activities and to offspring during pregnancy. It can tell you if you're at risk for developing AIDS. Further tests will assist us in determining how your body's defenses (immune system) are working right now."

Continue to reflect and restate your patient's feelings. "It sounds like you are feeling terrified and helpless because you see the virus as a bomb inside of you which is ready to go off." Since you cannot surgically remove the virus or the emotional pain of the moment, it is critical to offer the patient the confidence that he or she will, with time, develop the ability to adjust to this new reality. The way the individual adjusts, it is hoped, will support good health care and disease-control measures. The physician has to walk a fine line between acknowledging the reality of HIV - life with a typically degenerative, transmissible, and fatal disease - while projecting hope that with the combination of current medical advances and the patient's personal efforts to stay well, he or she can live an active and productive life. Hope is neither a false promise nor a guarantee about the future; it is, on the contrary, a powerful gift.

Step 6: Develop Medical Follow-Up Plan for HIV+

Some physicians provide follow-up HIV-related assessment and care directly, while others secure these services through personal referral to another setting. Review recommendations for medical follow-up with the patient and explain what will come next and why, including TB screening, an immunological work-up, and reproductive health counseling. Let the patient know that treatment options will be considered when these results are evaluated. You can start to empower the patient and define the current limitations of medical intervention by saying, "While at this time we don't have a drug which can cure HIV, there is a lot that we can do, including all the ways you can take good care of your health."

Encourage the patient to start learning about HIV disease. Advise him or her that more informed patients often cope better. Talk about the importance of avoiding other infections such as sexually transmitted diseases, and of the beneficial effects of exercise and good nutrition. Talk about the benefits of involvement in counseling and peer support groups. These concrete suggestions help the patient to consider ways of regaining a sense of personal control. It also communicates your expectation that the patient can cope and join you in a health care partnership.

For referral to the MDPH Behavior Resources Program, an information and support group for HIV positive persons, call (617) 522-3700 x473.

Step 7: Review Risk-Reduction Guldelines and Plan

Critical to an HIV+ individual's well-being is his or her capacity, with time, to resume living fully while incorporating necessary changes in behavior and lifestyle decisions. Upon learning their status, many individuals feel contaminated, as if they can pass the virus casually. Restate the obvious, saying, "You may be feeling that you can pass the virus any which way; however, let me reassure you that it's not transmitted casually - hugging, preparing meals, playing with your kids are all safe."

At the time a test result is given, seropositive patients will have little attention to direct toward a discussion of risk reduction. All you should expect to provide is a review of risk behaviors specific to the patient's lifestyle and ways of modifying them. You might say, "Let's go over what you think risk reduction will look like for you." Follow up on outstanding issues, "How did it go when you called the drug rehab program?" Clarify misinformation about transmission. "Your HIV-negative test result cannot tell you whether your boyfriend has the virus and can pass it to you in the future through unprotected sex. He must take the test to find out if he is infected. Remember, he can look fine and still have the virus." Provide the patient with the appropriate prevention literature.

Step 8: Review and Implement Partner Notification Plan

It is difficult to focus the discussion away from the patient's immediate concerns and onto his or her responsibility for current or past partners. Restate the importance of completing this task and ask if the patient has given thought to how partners will be notified. You might say, "Let's look at who might have been exposed to HIV and how they can be advised of their possible risk. There are a number of ways they can get this information without violating your confidentiality."

Step 9: Review Confidentiality Issues

Ask the patient if he or she wants to discuss how to protect the confidentiality of the test result.

Step 10: Mobilize Support System

The time will come when the patient must leave the office. This transition can be facilitated by saying, "Tell me what you're going to do in the next 24 hours." Some patients will need concrete help figuring out how they are going to get home safely. Help the patient identify at least one person to whom he or she can turn for support.

Step 11: Summarize Plans for Referral and Follow-Up

Write out the action plan and review it with the patient. It should include medical and social support, prevention, and notification activities. Remind the patient that ultimately, he or she has control over how to use these resources. Assure the patient that you are here to help. Schedule a follow-up appointment.

Appendix III

Clinical Manual for Care of the Adult Patient with HIV Infection

Department of Medicine, Boston City Hospital Howard Libman, M.D., Robert A. Witzburg, M.D., Editors

Just published, this comprehensive manual for health providers offers up-to-date, clinically-oriented, practical information on the care of patients infected with HIV. Approximately 300 pages, the text is divided into four sections:

Overview of HIV Infection

Natural History and Staging Serologic Diagnosis Laboratory Testing

Clinical Manifestations

Fever
Weight Loss and Malnutrition
Generalized Lymphadenopathy
Oral Manifestations
Ocular Manifestations
Dermatologic Manifestations
Pulmonary Manifestations
Neurological Manifestations
Gastrointestinal Manifestations
Hematologic Manifestations
Renal Manifestations
Psychological Manifestations

Opportunistic Diseases

Pneumocystis Pneumonia
Mycobacterial Meningitis
Cryptococcal Meningitis
Toxoplasmosis
Syphilis
Cytomegalovirus Infection
Herpes Simplex/Varicella Zoster Infections
Candidiasis
Bacterial Infections
Kaposi's Sarcoma
AIDS-related Lymphoma

Special Topics

AIDS Education/Prevention Antiretroviral Therapy Asymptomatic HIV Infection Infection Control/Risk Reduction Reluctance to Provide Care Homosexual/Bisexual Patient Legal Issues

To purchase *The Clinical Manual for Care of the Adult Patient with HIV Infection*, fill out this information and mail a check for the appropriate amount to the address below. Inquiries about bulk purchases are welcome (include telephone number). Please print or type.

Name		
Organization/Agency		
Address		
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No. of copies X \$30.00/copy =	\$	Return this form to:
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Sales tax (MA residents only) @ \$1.50/copy =	+	Box 306 Sherborn, MA 01770
TOTAL AMOUNT (enclosed) =	\$	

Appendix IV

HIV Counseling and Testing Services

Alternative Test Site Program

The ATS program offers both scheduled and walk-in appointments for **anonymous** testing and counseling. Sites for scheduled appointments are listed first, followed by walk-in locations. To schedule appointments, except where otherwise noted, call (617) 522-3700, x470 or x471, or call collect (617) 522-4090. An asterisk (*) denotes clinics that offer bilingual services.

Scheduled Appointments (anonymous)

Metropolitan Boston

Massachusetts General Hospital, Boston Somerville Hospital, Somerville Lawrence Memorial Hospital, Medford Fenway Community Health Center, Boston, (617) 267-0159 *

Northeast Region

Haverhill Board of Health, Haverill HealthQuarters, Beverly

Western Massachusetts

University of Massachusetts Health Services, Amherst Baystate Medical Services, Springfield Red Cross, Pittsfield Family Planning of Western Massachusetts, Holyoke

Cape Cod

Outer Cape Health Center, Provincetown

Walk-in Appointments (anonymous)

Metropolitan Boston

Boston City Hospital, Boston *
Ambulatory Care Center Public Health Clinic, 3rd floor

Monday Tuesday Wednesday Thursday Friday 2 - 4pm 2 - 4pm

Dimock Community Health Center, Roxbury * Linda Richards Bldg, X-ray Dept.

Monday Tuesday Wednesday Thursday Friday 4 - 7pm

Alternative Test Site Program - continued

Cambridge City Hospital, Cambridge * Outpatient Department

Monday

Tuesday 5 - 7pm

Wednesday

Thursday

Friday

Southeast Region

Stanley Street Treatment Center, Fall River * ATS Clinic, (508) 679-5222, x226

Monday

Tuesday 3 - 6pm Wednesday 4 - 8pm Thursday 9 - 11am

Friday

Central Massachusetts

Framingham Union Hospital, Framingham Public Health Clinic, LuAnn Karb, RN

Monday

Tuesday 8:30 - 11:30am Wednesday

Thursday

Friday

Worcester City Hospital, Worcester

Public Health Center, (508) 799-8276, Anne Decelles, RN

Monday

Tuesday

Wednesday

Thursday 12 - 4pm Friday

Western Massachusetts

Brightwood Riverview Health Center * (413) 784-4458, Pura Dion

Monday

Tuesday

Wednesday 9am - 12pm

Thursday

Friday

Sexually Transmitted Disease Clinics

The following STD clinics offer both scheduled and walk-in appointments for confidential counseling and testing. Confidential testing requires the name of the patient to be given. Please call for scheduled appointment. An asterisk (*) denotes clinics that offer bilingual services.

Scheduled Appointments (name required)

Metropolitan Boston

Beth Israel Hospital, Boston (617) 735-4087

Western Massachusetts

Berkshire Medical Center, Pittsfield (413) 443-1619

Sexually Transmitted Disease Clinics - continued

Walk-in Appointments (name required)

Metropolitan Boston

Beth Israel Hospital, Boston * (617) 735-4087, Carol London, RN

 Monday
 Tuesday
 Wednesday
 Thursday
 Friday

 9 - 11:30am
 9 - 11:30am
 9 - 11:30am

 1 - 4pm
 1 - 4pm
 1 - 4pm
 1 - 4pm

 5:30 - 8:30pm
 5:30 - 8:30pm

Boston City Hospital, Boston * (617) 424-4081, Diane Duffy, RN

Monday Tuesday Wednesday Thursday Friday 8:30 - 10:30am 8:30 - 10:30am 8:30 - 10:30am 8:30 - 10:30am 1 - 2pm 1 - 2pm

Massachusetts General Hospital, Boston (617) 726-2748, Melinda Sohval

 Monday
 Tuesday
 Wednesday
 Thursday
 Friday

 8:30 - 11am
 8:30 - 11am
 8:30 - 11am
 8:30 - 11am

Northeast Region

St. Joseph's Hospital, Lowell * (508) 453-1761, x1625, Connie Niedzwiecki, RN

Monday Tuesday Wednesday Thursday Friday 3:30 - 5:30pm 11:30am - 1pm

Holy Family Hospital, Methuen * (508) 687-0151, x2432, Mylene Cassell, RN

Monday Tuesday Wednesday Thursday Friday 4 - 5:30pm

Southeast Region

St. Luke's Hospital, New Bedford * (508) 992-3855, Rosa Hernandez, RN

Monday Tuesday Wednesday Thursday Friday 9 - 11am 12-2 pm

Central Massachusetts

Framingham Union Hospital, Framingham (508) 626-3540, LuAnn Karb, RN

Monday Tuesday Wednesday Thursday Friday 6 - 8pm 1-1:30 pm

Sexually Transmitted Disease Clinics - continued

Worcester City Hospital, Worcester (508) 799-8276, Anne Decelles, RN

Monday 8-10:30 am Tuesday 8-10:30 am 5:15-6:30 pm

Wednesday 8-10:30 am Thursday 8-10:30 am Friday 8-10:30 am

Western Massachusetts

Springfield Health Department, Springfield * (413) 787-6129, Vickie Watson, RN

Monday 10-11:30 am Tuesday 10-11:30 am 1-5 pm

Wednesday

Thursday 10-11:30 am Friday

Substance Abuse Treatment Facilities

HIV counseling and antibody testing is provided in connection with substance abuse treatment programs at the following nine locations. This service is anonymous and intended for clients enrolled in treatment programs. Counseling and testing are by appointment.

Metropolitan Boston

Boston City Hospital/Project Trust, Boston (617) 424-5554

Dimock Community Health Center, Roxbury (617) 442-2121

Concilio Hispano, Cambridge (617) 661-9406

Northeast Region

Centro Panamericano, Lawrence (508) 794-0125

Southeast Region

New Bedford Area Center for Human Services/Project Care, New Bedford (508) 999-2321

Stanley Street Treatment and Resources/Project Aware, Fall River (508) 679-5222

Central Massachusetts

AIDS Project Worcester, Worcester (508) 756-5532

Western Massachusetts

Providence Hospital/Elm Street Health Center, Holyoke (413) 536-7383

Northern Educational Services, Springfield (413) 737-8523

Appendix V

Resources of the Massachusetts Department of Public Health

Massachusetts Department of Public Health 150 Tremont Street Boston, MA 02111

AIDS Office, (617) 727-0368
Policy development, Health services, Client advocacy/minority programs, Public information

AIDS Education and Training, (617) 727-0368
Regional coordination, Adolescent education, Minority outreach, Women's and pediatric issues

Regional AIDS Education

Central Region

AIDS Program Central Regional Health Office Rutland Hospital Rutland, MA 01543 (508) 886-4711, x323

Northeast Region

AIDS Program Northeastern Regional Health Office Tewksbury, MA 01876 (508) 727-7908, x684

Southeast Region

AIDS Program Southeastern Regional Health Office Lakeville Hospital Lakeville, MA 02347 (508) 947-1231, x572

Western Region

AIDS Program Western Regional Health Office 23 Service Center Road Northampton, MA 01060 (413) 586-7525, x63 MA Centers for Disease Control (MCDC) AIDS Program 305 South Street Jamaica Plain, MA 02130

Administration (617) 522-3700, x485

Counseling and Testing Alternative Test Site (ATS) Program (617) 522-3700, x470, x471, or x474

HIV Counseling and Testing Training Program (617) 522-3700, x494

Behavioral Resources Program (BRP) Information, Support, and Referral for HIV+ asymptomatic persons

Boston

Massachusetts Department of Public Health (617) 522-3700, x472 or x473

Martha Eliot Health Center (617) 522-5300, x206

Dimock Community Health Center (617) 442-9825

Northampton

Massachusetts Department of Public Health (413) 586-7525

Surveillance and Seroprevalence (617) 522-3700, x482 or x478

Sexually Transmitted Diseases (STD) Program (617) 522-3700, x416

Partner Notification (617) 522-3700, x403

Appendix VI

Project Inform Discussion Paper #1 HIV Treatment Strategy

1/12/89

HIV and the Immune System

AIDS and ARC are the most serious forms of a single illness caused by a powerful virus, called Human Immunodeficiency Virus (HIV). The virus attacks specific cells in the immune system, which it can destroy or cause to malfunction. Thus, HIV disables the very system of the body which should be responsible for fighting it. When the immune system is damaged by this virus, it loses the ability to combat other illnesses and infections. As the disease progresses, these other diseases, called opportunistic infections, attack the body, further wearing down the its defenses. These infections and cancers, such as pneumocystis pneumonia (PCP) and Kaposi's sarcoma (KS), are the real killers of AIDS.

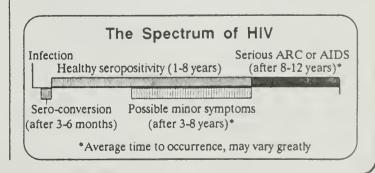
One critical immune system component which is attacked by HIV is the "T4" or helper cell. These cells trigger the body's immune response against infection. Without them, the rest of the immune system cannot function properly. One of several things can happen when HIV attacks T4 helper cells:

- 1. The virus enters and takes control over some T4 cells; each infected T4 cell becomes a virus factory, producing new virus and releasing it into the bloodstream where it can attack other cells. Over time, the original T4 cell dies.
- 2. Some infected helper cells live with virus controlling them; in this form, they attach to other T4 cells. This is called cell-to-cell infection. When infected cells attach to other T4 cells, they form clusters of infected cells which may also produce new virus. These clusters are incapable of functioning properly and die quickly.
- 3. Parts of the virus' shell (proteins), which are produced even when whole virus is not, begin to appear on the surface of infected and even unifected cells, making them look like the virus to the immune system. Antibodies, produced to tag the virus for destruction by "killer cells," now also mark these cells which carry the mark of the virus. Thus, the immune system begins to attack itself, destroying healthy cells along with infected ones.

As the total number of T4 cells falls, the body slowly loses its ability to resist infection. Although the body is contantly producing new T4 cells to replace those lost, it cannot sustain the loss of T4 cells indefinitely. Repeated T-cell testing over time can measure the decline of T4 cells. This test determines the number of T-4 cells in a sample of the blood, presumed to be typical of all the blood. In every AIDS-related study, low T4 counts have corresponded to more frequent and more serious opportunistic infections. Thus, T4 testing has become the most common way to monitor the decline of the immune system.

When the epidemic began, we only heard about AIDS. Later, the term ARC was created as more and more conditions came to be seen as AIDS-related. We now realize that HIV infection generally progresses to AIDS, either slowly or quickly. Without treatment, even the least severe stage of the disease, called persistent generalized lymphadenopathy ("PGL" or swollen lymph nodes), leads gradually to more serious illnesses. Recent long-term studies have researched the rate at which the disease progresses. One study concluded that, if untreated, infection with HIV (being "seropositive") leads to AIDS or some form of symptoms in 7 years for 78% of the people studied. Another study puts it differently, saying that 41% have AIDS or serious ARC after 6 years; another predicts that 65 - 100% will develop AIDS after 16 years, with the average time to AIDS being 12 years. What all such studies conclude is that HIV is a progressive infection which leads to symptomatic illness in the majority of people over time. These figures are compiled from the experiences of the gay community, the first and still largest group affected in this country. Children born with HIV and people infected through blood transfusion seem to get sick more quickly. Studies with women and hemophiliacs are inconclusive about the rate of progression. As yet, though, no group has shown the ability to develop immunity to the virus.

HIV is now considered a "spectrum" illness: all who are infected have the same disease, though there are many stages to it. Today, it is simply called HIV infection or HIV disease, rather than AIDS. AIDS is the most serious of 6 recognized stages of the disease. Each stage is defined by the occurence of certain infections, symptoms, or the lack of them. In the least serious stage, people are seropositive, meaning that they have tested positive on the HIV anti-body test, though they are unaware of any illness. If untreated, those who are infected move along the spectrum as HIV gradually destroys T4 and other immune system cells, damaging the body's ability to fight off infection. Recent studies suggest that infected people lose approximately 10% to 15% of their total T-cells, on average, per year.HIV also infects cells in the central nervous system. Recently, scientists have found that the virus infects bone marrow, where red and white blood cells are produced.



HIV Treatment Strategy

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Treatment Strategy

In general, T4 cells decline to lower levels long before the infections associated with AIDS or ARC occur: a person first becomes immune deficient and then goes on to experience opportunistic infections. By monitoring the T4 count, we get a rough picture of the condition of the immune system. Having this information can help a person avoid infections and know when and how to treat the immune deficiency.

When people know where they stand and learn what they can do about it, they no longer need to be taken by surprise by opportunistic infections. Unfortunately, most of us have been trained to wait until a disease shows up before doing anything about it -"if it ain't broke, don't fix it." We need to understand that the immune system starts to "break" at the point of infection with HIV, not just when opportunistic infections show up. Thus, monitoring the health of the immune system is critically important.

Monitoring immune Health

There are two common approaches to monitoring immune health, each with its advantages and disadvantages.

1. SYMPTOM OBSERVATION:

This approach is based on the evidence presented by active infections and disease processes. In HIV, this means watching out for such things as thrush, pneumocystis, KS lesions, and so on.

Advantages

It is easier to believe and take action when we are faced with an obvious illness. People who feel sick usually want to treat the illness as soon as possible.

Disadvantages

HIV may progress quite far before symptoms appear, without patient awareness. By the time symptoms appear, options for treating the problem may be less effective because the body is left with only limited defenses.

2. LAB STUDIES AND BLOOD ANALYSIS

- a) anti-body testing
- b) T-cell testing
- c) p24 and beta-2 testing d) CBC-basic blood studies

Advantages

Indications of illness show up well before illness becomes apparent. Taken together, the tests enable patient and doctor to act to prevent serious infections before they occur.

Disadvantage

It is more difficult to act on test results, since the patient often feels fine. People who feel healthy may be less motivated to begin treatment. Test results are variable, changing for many reasons.

Because HIV infection can be a life-and-death matter, we believe it is critical to choose the second approach. Taking a preventive approach makes it possible to:

- use treatments at the stage in which they are most effective
- · head off serious opportunistic infections and the further damage they do the immune system
- · slow the spread and reproduction of the virus.

Some people hesitate to act in a preventive manner because the treatments currently available are not perfect and the research on them is incomplete. Thus, they feel it might be best to wait for better treatments. However, no one knows when better treatments will become available - many hopes have been raised and dashed before. Although we don't know precisely the results of using current treatments in every case, we DO know what happens without treatment:

Once infected by HIV, people do not get better naturally or by waiting. There is no natural remission.

The purpose of preventive treatment is to buy time, to slow the progress of the disease while researchers seek better treatments. Once infected, people have only one chance to manage HIV disease correctly. A preventive approach is the only one which offers clear hope.

Reducing Variability in T-Cell Testing

T-cell testing produces widely varying results. Some physicians fear that T-cell testing may be so variable as to be unreliable. There are two kinds of variations which affect the T4 count: real variations which reflect a person's immune health, and insignificant variations caused by factors unrelated to immune health. Thus, we need to know what causes these artificial, misleading variations and how to minimize them to get a more reliable picture of immune health. The value of T4 monitoring can be improved when you:

- Look for trends, not individual numbers No single T4 test gives a complete picture of immune health. Ideally, T4 tests should be taken at least on a quarterly basis (every 3 months) for those with counts around or below 500, or every 6 months by those with higher counts. It is the overall trend of the numbers which tells which way things are going.
- Test at a consistent time of day Early in the day and before eating, fewer of the T4 cells are circulating in the blood, and thus the count may be lower.

Later in the day, more are in circulation and the numbers are likely to be higher. By testing at the same time of day, the numbers from one test to the next can be more validly compared.

- Use the same lab for testing each time
 Different labs use different techniques and machines,
 producing different results. Work with your doctor to be
 sure the test is done at the same lab each time.
- Testunder normal conditions, avoiding periods of infection
 Even minor infections can affect the T4 count and give
 misleading results. A second blood test, called the ESR or
 sedimentation rate, can also be run, which may indicate
 whether the body is fighting infections, even if you are
 unaware of them. If an active infection is present, either
 delay the test or repeat it later to get a more accurate
 picture. If an ESR test suggests an infection was present at
 the time of testing, don't take the T4 count numbers too
 seriously.
- Avoid acute stress, recreational drugs, and lack of sleep
 Acute stress (not everyday stress) can lower T-4 counts in
 some people. This effect is often greatest in periods of
 loneliness, depression, or lack of support. Drug use and
 lack of sleep can lower T4 counts.

The best way to achieve meaningful and comparable results in T-cell monitoring is to create a standard or routine climate for testing, so that variations which affect the count are held to a minimum.

Other Types of Testing

In recent years, other tests have become available which help measure immune health or reflect the progress of HIV infection. Using these additional tests gives a more accurate picture than that provided by T-cell testing alone. Three important tests are called p24 antigen, p24 antibody, and the beta-2 microglobulin test.

P24 ANTIGEN TEST:

What is it?

This test measures the level of a particular protein produced in the "core" of HIV. This protein or antigen, is known to scientists as "p24." Normally, the body produces antibodies to rid itself of antigens. When p24 antigen can be measured in the blood, the virus is believed to be actively reproducing itself so rapidly that the body cannot produce enough antibodies to overcome it. When this occurs, healthy cells may be infected at an increased rate. This imbalance between antigen and antibody is thought to occur for a brief period

shortly after infection, and again much later when the immune system is breaking down at a more rapid rate.

What does it show?

Studies have found that people with high p24 antigen level (sometimes called a "positive" test result) are more likely to progress to a full AIDS diagnosis in the next few years, even if their T4 count doesn't suggest immediate danger. Thus, a positive or high p24 antigen test result is a serious warning sign.

P24 results are often reported as simply positive or negative, although the test actually measures the amount of p24, reported as a number. Numbers below 40 or 50 are called negative, numbers above, positive. A typical positive result might be a reading of 100 to 400, but can range into the thousands. The degree of positivity (how high the number goes) has so far not been shown to correspond to the risk of disease progression, that is, all results reported as positive suggest the same increased risk. However, no firm predictive value has yet been established for p24 readings for people already diagnosed with AIDS.

How is it used?

P24 is almost universally used in clinical studies to measure the effects of anti-viral medications. Many physicians recommend the test to determine when to treat aggressively and to measure the effects of treatment. This test is still classified as "investigational" by the FDA, and is not always available in every lab or every city. (Both p24 antigen and antibody tests can only be given to people who have tested positive in the usual HIV antibody tests.)

P24 ANTIBODY TEST

What is it?

High levels of antibodies to the p24 antigen seem to slow the progression of HIV. This test measures the level of these protective antibodies to p24 in the blood.

What does it show?

Antibodies and antigen normally bind together like lock and key. High levels of p24 antibody suggest that the bodies defenses are still working properly and that new virus particles are rapidly being cleared from the body. Typically, p24 antibody levels remain high while the patient experiences few or no symptoms, then diminish over time. When p24 antibody levels have fallen, the p24 antigen can become detectable in the blood. So far, there is little understanding of what causes the drop in p24 antibody levels.

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Thus, p24 antibody levels might be an earlier predictor of HIV progression in some people. One study showed that p24 antibody levels became negative up to 18 months before the first p24 antigen test became positive. When p24 antigen and p24 antibody are both positive, the body may be experiencing an "auto-immune" disorder, in which the immune system is attacks healthy cells and tissues.

How is it used?

Like the p24 antigen test, the p24 antibody test is still investigational and is even less widely available. The test is useful only as a predictor of HIV progression and has no established value in monitoring the effects of treatment.

BETA-2 MICROGLOBULIN TEST:

What is it?

The beta-2 microglobulin test measures the presence of a tiny protein particle found on almost all cells, including the T4 and other cells which HIV can infect or destroy. As cells die, the beta-2 is released in the blood. Thus, there is always some degree of beta-2 in the blood as a result of normal cell degeneration and replacement. In chronic illnesses, such as HIV, the level of beta-2 increases beyond normal levels, reflecting a more rapid rate of cell destruction.

What does it show?

Studies show that people with a high beta-2 level are much more likely to progress to AIDS in the near future. Some researchers believe this test to be the most accurate of all predictors of progression to AIDS.

Beta-2 levels are usually reported as a single digit number, carried out to one decimal place, such as 2.3, 3.5, or 5.2. A number of about 2.6 or below is considered normal. A level of 5.0 or higher indicates the highest known risk of coming down with AIDS within 3 years. Even persons with readings between 3.0 and 5.0 are at increased risk.

How is it used?

Since beta-2 testing in HIV is new, its uses are still being researched. It seems likely that it will be used to monitor the effects of treatment and to identify patients who are at highest risk of an impending AIDS diagnosis. Other indirect markers, such as neopterin levels, are also being investigated as potential measures of HIV progression.

SUMMARY: TESTING

While no one of these tests gives a total picture of immune health, taken together they are very important. Some researchers believe that as we learn to manage HIV as a chronic illness, these tests will provide guidance about what treatments to use, when to use them, and how well they are working. Because some of these tests are new, they may not be as accurate as we'd like. Also, because of potential inaccuracies or misunderstandings of their proper use, some physicians are skeptical of their value or the cost of using them. Over time, these and other tests are likely to become the standards tools for monitoring and managing HIV infection.

HIV Treatments - Three Types

Managing HIV infection may require three types of treatment: anti-virals to slow the reproduction of the virus and prevent further cell-to-cell infection, immune modulators to help strengthen the immune system, and preventive measures against opportunistic infections (known as Ols). This triple-barreled approach, called combination therapy, will be the best choice unless a "magic bullet" is found which can eliminate HIV and its consequences altogether.

ANTI-VIRALS:

Purpose:

To slow or stop the progress of the virus in the body; only one, AZT, is licensed for use against HIV, while two others, acyclovir and ribavirin, are licensed for use against other viruses but may have a role in treating patients with HIV.

Goal:

To stop further deterioration of the immune system and further infection of the central nervous system and bone marrow.

Use:

Use of an anti-viral can be discussed with your physician as soon as infection by HIV is diagnosed, without waiting for the appearance of symptomatic illness. Use is critical when there is indication of seriously declining T4 cells, or high p24 antigen or beta-2 levels.

IMMUNE MODULATORS:

Purpose:

To help rebuild a compromised immune system in ways that are measurable by blood tests and by improved clinical health.

Goal:

To increase the number of functional T4 cells and/or restore the balance of the various components of the immune system; this

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enables the body to better resist opportunistic infections and to help keep HIV in check.

Use: Im

Immune modulators should be discussed with your doctor when the trend of T4 counts declines toward the levels at which ARC symptoms first appear (typically around or below 400).

"OI" PREVENTATIVES:

Purpose: To prevent potential infections.

Goal: Prevent the occurrence of the most common opportunistic infections, or prevent their

return after a first occurrence; this allows the body to retain its strength for fighting the

underlying HIV infection.

Use: OI preventatives should be discussed with

your doctor when T4 counts are in or nearing a danger zone (for example, the risk of PCP becomes high at T4 count of 200 or below).

Discussion - Starting Points

The earliest possible treatment is recommended for just about every known illness. There is little reason to think that HIV is any different. In fact, early treatment may be even more important because of the seriousness of the disease.

STEP ONE in early treatment is the HIV anti-body test. Because we now know that most of those infected develop AIDS or symptoms of immune deficiency within 7 years, the test clearly has predictive value. It says that a viral infection has occurred, and might have been active already for years. Thus, the best time to start treatment may be right now.

ANTI-VIRALS:

Starting points for the use of anti-viral, immune modulating, and OI preventative medications are the subject of much disagreement. Many people believe that anti-viral medication is appropriate immediately upon learning of the infection, whether or not the T4 count is falling or whether symptoms are evident. Waiting longer might only let the infection progress as it slowly damages more and more T-cells and spreads to other parts of the body.

Others, however, disagree expressing two arguments. Some people feel that, since HIV infection seems dormant for long periods, during which no major visible damage occurs, that there may be little point to treating an inactive infection. Others counter that damage to the immune system is always

taking place, although perhaps at levels too low for current tests to detect. Thus they feel anti-viral medication is appropriate at the earliest possible moment, when it can perhaps prevent further spread of the virus. They also note that healthy seropositives have far less trouble with the sideeffects of such drugs as AZT. In apparent support of this theory, a number of major AIDS hospitals have begun treating staff workers with a potent anti-viral (AZT) immediately after accidental infection (e.g., by needle sticks). Among others, Dr. William Haseltine, a prominent AIDS researcher, recommends AZT for all HIV-infected people, starting from the first knowledge of infection. A nationwide study of 3000 healthy seropositives, using AZT, is currently attempting to determine whether this is the right approach. A number of the researchers involved are hopeful, if not confident, that the study will prove the value of this approach.

Some physicians caution against early use of anti-virals on the grounds that current medicines, such as AZT, may cause serious long-term side effects. They fear that early treatment might do more harm than good. Instead, they recommend that patients wait until they absolutely need treatment, in hopes that by then, less toxic medicines will be available. Although this view was common early in the epidemic, it is increasingly revised as new data is developed about early treatment. The latest AZT studies show that anti-viral treatment at early stages seems to slow progression toward AIDS and that side effects are less severe, or even non-existent, in healthier patients. The side effects of AZT are now well-known and can be delayed or prevented; the effects of HIV aren't nearly so manageable or reversible.

There is less argument about the need to start anti-virals when symptoms are present and the T4 count is falling., and the p24 antigen test is positive. Although the original FDA approval of AZT required that patients have a T4 count of 200 or less, this arbitrary threshold has since been abandoned by just about everyone except the insurance companies who have to pay for AZT. Insurance companies, for short-sighted financial reasons, frequently refuse payment for anti-virals at early stages of HIV infection. This practice, however, should not be confused with sound medical judgment. Patients at all stages of HIV infection should be prepared to fight for their rights to reimbursement for anti-viral treatment. Insurance companies with a long-term view and some common sense see that it is less expensive to pay for preventive treatment now than for hospitalization later.

IMMUNE MODULATORS:

The starting point for using immune modulators can be based on T-cell counts. When the count is sufficiently high, there are enough T-cells to trigger an effective immune

response. When the count falls too low, however, it is very difficult to get it back up again without immune modulators. In short, you must have an immune system to rebuild one.

T4 Cell Ranges

Lowest	Low	High
(under 200)	(200-500)	(500 plus)

High Range: In general, a T4 count of 500 or above suggests no immediate danger. The 500 level is often cited as the bottom of the "normal" range, but this can be misleading. While an occasional drop to 500 may be normal, a steady or slowly falling count of 500 or even 600 is not and indicates suppressed immunity (but no immediate danger of AIDS). At the very least, T-cell monitoring and periodic use of other tests are recommended in this range, whether or not anti-viral medications are used. With counts this high, many people feel little motivation to begin treatment. A growing number of reseachers, however, believe it may be the best time to do so.

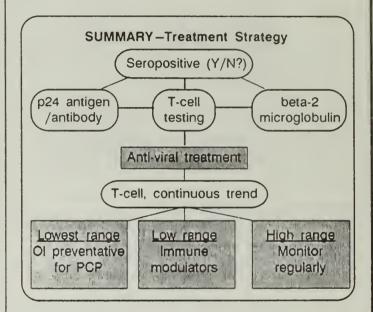
Low Range: Studies of ARC often exclude patients with more than 500 T4 cells because ARC symptoms are uncommon above this level. Still, it is well known that some ARC conditions and even KS can occasionally strike people with T-4 counts above 600. Therefore, as a general guideline, when the T-4 count falls around or below 500 on two consecutive tests, or if it shows a steady decline toward 500 in repeated quarterly tests, immune modulators may be appropriate.

Lowest Range: T4 counts below 200 indicate the greatest risk of infections. This level is common among AIDS patients. There are exceptions, but even people in this range who seem healthy have greater difficulty combatting OI's when they occur. Treatment includes preventive therapy against common opportunistic infections. While some people have additional warning signs in the form of symptoms before majorinfections occur, this is definitely not always the case. Some progress directly from apparent health to serious OIs.

OI PREVENTATIVES

In the studies of AZT, it was found that patients with T4 counts of 200 or less were far more likely to get PCP and other infections. It has become common to put seropositive patients with T4 counts near or below this number on preventive treatment against PCP (for example, aerosolized pentamidine), as are almost all patients who have suffered an initial bout of pneumocystis. Today, some insurers and state health plans refuse to pay for such treatment unless the patient has already had the infection. Based on current studies about to be published, there will soon be no ethical excuse for denying such treatment.

Aerosolized pentamidine is one of the most popular PCP preventatives and it offers the promise of minimal side effects because the drug is not circulated throughout the body. This approach, however, is expensive, inconvenient, and available everywhere. Thus, oral doses of drugs such as Septra, fansidar, and dapsone are often used. While these are more convenient and less expensive, they may be more likely to produce side effects in patients with advanced disease. One drug, fansidar, has been responsible for numerous deaths from side effects and Project Inform and others urge patients to refuse it.



Available Treatments

Project Inform provides complete information on the purchase and use of a carefully selected group of HIV treatments. To be included on this list, a treatment must meet three important criteria:

- 1. ESTABLISHED SAFETY the treatment must be shown, by valid, independent testing, to be safe for human use at the dosage suggested for treatment.
- 2. AVAILABILITY the treatment must be available to the general public, over-the-counter, by prescription, or from another country.
- REASONABLE HOPE OF EFFECTIVENESS there
 must be good indications, if not conclusive proof, that the
 treatment may work; this may be established by clinical
 trials or systematic observation of patient use.

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To date, Project Inform supplies standard information on only about 10 treatments on a list which changes over time. While there obviously are other treatments, some of them in common use, these have usually not met our third criteria. It may be that some such treatments will later prove useful, but they are not yet supported by sufficient data to be considered reasonable choices by our definition. Project Inform is as much interested in pointing away from useless, expensive, or completely unproven approaches as it is in pointing toward those which offer the best hope now.

We believe that these and any other treatments should only be used under the care of an experienced physician. We encourage patients and physicians to enter into creative, collaborative relationships in which they share responsibility for achieving and maintaining health. The choice of treatments need not be dictated by either party, and each should strive to understand the other's concerns and requirements if disagreement arises. Treatment should always be accompanied by monitoring which evaluates the success for failure of treatment. Both patient and physician should be prepared to adjust strategy based on the results of the monitoring process. This model of flexible, monitored treatment use in the context of a collaborative doctor/patient relationship is the key to managing HIV as a chronic illness.

Treatment for HIV must always be supported by an overall commitment to a healthy lifestyle. We encourage people to review their health habits and take action in those areas which need strengthening. These include nutrition, sleep, stress management, social support, exercise, and emotional matters. Once a treatment strategy has been established, many people also explore the possible benefits of nontraditional, holistic or alternative approaches, including acupuncture, herbal remedies, vitamins, meditation, and so on. We believe it is a dangerous mistake, however, to use alternative or holistic methods to the exclusion of the medicines recommended by physicians. Whatever paths are chosen, substance abuse - with alcohol or other drugs - is incompatible with immune health and acts to undo the benefits attained by any therapy.

Complete information on the treatments listed below, in laymen's terms, is available from Project Inform, along with aseries of discussion papers on related topics. Just ask for the basic "treatment package." The latest information on these and other important treatment issues is available through the Project Inform hotline. Hotline hours are Monday through Friday, 10:00 am to 2:00 pm (Pacific time).

	Project	Inform	Treatm	ent List
		(by gr	oup)	
	HIV tivirals	Imm Modu		"OI" Treatments
alpha	AZT interferon an sulfate	alpha interferon Antabuse/DTC DNCB	se/DTC	acyclovir PCP prophylaxis
ribavirin	2.102		Uncategorized	
		Active lipids		

For complete information on availability, pricing, dosage, pros and cons, call for the Project Inform basic information packet.

Project Inform: Mission and Services

Mission:

- Research assessment and education (for patients, physicians, and the media)
- Outreach and advocacy on early diagnosis, immune health monitoring, and treatment availability
- Anecdotal data collection
- Helping to shape national policy on access to treatment and research practices

Services:

- · Treatment information hotline
- Mailing service supplying treatment information; patient packets and physician packets
- · Quarterly newsletter
- Town meetings
- "Special request" services

PROJECT INFORM

347 Dolores St., Suite 301

San Francisco, CA 94110

HOTLINES:

Cal. 1-800-334-7422 Nat. 1-800-822-7422

Local: 415-558-9051

Appendix VII

Guide to Obtaining AIDS-Related Drugs

The following resources are available to help uninsured or under-insured HIV-infected persons gain access to treatments. For further information, please call the numbers listed:

Massachusetts HIV Drug Relmbursement Plan

A federally funded program covering the costs of AZT, aerosolized pentamidine, and alpha interferon. (617) 262-0889 or 1-800-228-2714.

Pediatric Treatment IND

A program offered by Burroughs Wellcome, in coorperation with the National Institute of Allergy and Infectious Disease (NIAID), to facilitate the use of AZT for children who are infected with HIV. 1-800-829-7337.

Aerosolized Pentamidine for the medically indigent

A program offered by Lyphomed to distribute pentamidine to community health centers for the benefit of persons unable to pay for treatment. 1-800-727-7003.

A Special Note on Access to Aerosolized Pentamidine Treatment

Aerosolized Pentamidine (AP) is offered in three types of settings: community health center clinics or physicians' offices, the outpatient departments of hospitals, and at home via home health care agencies. Some health center clinics, such as the Fenway Community Health Center in Boston, provide AP to patients who are referred by area physicians. Most major hospitals, especially teaching hospitals, provide outpatient AP treatment through their respiratory or pulmonary medicine departments. Home health care agencies, such as VNAs, deliver AP in all regions of the state. The treatment delivery system requires the use of both medical durable and disposable equipment. In some cases, patients receiving home health care provide their own equipment. In other cases, the health care agencies provide equipment rental. The cost of treatment, including delivery and equipment rental, is reimbursable by Medicaid and most third-party payors.

Appendix VIII

Consent Form Used by MDPH Alternative Test Sites

Alternative Test Site Program for HIV Screening Informed Consent Form

Please chec	ck off each item below to indicate that you have understood that point.
ident	derstand that this procedure is anonymous and absolutely confidential. The only tifying data is the code number I have been given. This code number can in no be linked to my name.
of the	ounselor has discussed with me the meanings of negative and positive test results ne HIV antibody screening. I understand that knowledge about what this test ns is not yet complete.
rea	alize the test results will not necessarily answer my concerns about AIDS.
have	ve not been forced in reaching my decision regarding this test. I realize that I e a choice about being informed of the results of my blood screening and that I re-evaluate my decision at a follow-up visit.
proce	a aware that I may experience increased anxiety in the course of having this edure or while waiting for test results. I acknowledge that I may be more anxious ving the test results.
Please print your accepted the above	code number on the following line to indicate that you have read, understood, and ve points.
	Code number:

Appendix IX

Order Form:

Guide to HIV Counseling and Treatment Among Adolescents

The Massachusetts Department of Public Health has coordinated an advisory group of representatives from state and community agencies to develop policies to address the particular HIV counseling and testing needs of adolescents. The policy document, to be published in the spring of 1990, will include two sections:

- 1. General principles to be followed when testing adolescents, with specific recommendations regarding voluntary testing, informed consent, confidentiality, and testing for research purposes.
- 2. A set of comprehensive guidelines for counseling adolescents on the test, including a five-session pre- and post-test counseling model recommended for use with adolescent clients.

	cy document, please fill out the information below:
Please send one copy o	f the Guide to HIV Counseling and Treatment Among Adolescents
Name	
Organization/Agency _	
Address	
Telephone	Date
Return this form to:	Adolescent HIV Counseling and Testing Policy AIDS Office Department of Public Health

150 Tremont Street Boston, MA 02111

Appendix X

Risk Factors for HIV Infection

HIV is a fragile virus that requires intimate contact for transmission. It follows that "What you do" is more important than "Who you are" in determining the risk of infection. The following factors increase the risk of HIV infection:

. Sharing needles and "works" (cookers and syringes) used to inject drugs.

- . Sexual intercourse (anal-genital activity) between men without the protection of latex condoms.
- . Sexual intercourse (penile-vaginal or anal-genital activity) with multiple heterosexual partners without the protection of latex condoms.

. Other sexual activities involving the exchange of semen, vaginal fluids, or blood.

- . A history of having received multiple blood transfusions and/or blood products between 1978 and July 1985.
- . Being a sex partner of someone in any of the above categories.

Note: The use of the vernacular may be more effective in determining risk factors than the use of clinical or euphemistic language. Safer sex literature available from AIDS service organizations such as the AIDS ACTION Committee offer definitions of risk factors in plain English.

Appendix XI

Legal Protection Against Discrimination

Legal protection available to people who have AIDS or ARC or who belong to one of the groups that appear to be a high risk is based on the interpretation that HIV disease, in any of its forms, is considered a handicap under federal law and state laws.

Under Article 114 of the Massachusetts constitution, it is unlawful to discriminate on the basis of handicap. The state civil rights statute allows a person who has been denied a constitutional right by threats, intimidation, or coercion to bring a lawsuit to seek redress.

The Massachusetts Commission Against Discrimination (MCAD) has extended the protections offered to the handicapped to persons perceived to be at risk of having AIDS. MCAD's policy prohibits discrimination in employment, public accommodation, and public housing.

The Massachusetts statute on confidentiality and disclosure of HIV information also prohibits HIV antibody or antigen testing as a condition of employment.

A Special Note on Health Insurance

It is lawful for insurance companies, with the informed consent of the applicant, to perform HIV screening on applicants for health insurance policies and to report results to the Medical Information Bureau, a national databank maintained by the insurance industry. It would be in the interest of the patient to have a group health insurance policy in place before testing.

Anti-discrimination Resources

Complaints of HIV-related discrimination should be directed to the following agencies:

Department of Health and Human Services, Office for Civil Rights
John F. Kennedy Building, Room 2403, Boston, MA 02203. Telephone: (617) 565-1340.

Attorney General's Department, Division of Civil Rights

1 Ashburton Place, Room 2010, Boston, MA 02108. Telephone: (617) 727-2200, x2903.

Massachusetts Commission Against Discrimination (MCAD)

1 Ashburton Place, 6th floor, Boston, MA 02108. Telephone: (617) 727-4146.

The Commission has set up a task force to investigate and resolve complaints of

HIV-related discrimination.

Massachusetts Division of Insurance, Consumer Service Bureau
280 Friend Street, Boston, MA 02114. Telephone: (617) 727-7189, x300.
The Consumer Service section of the Division handles complaints about insurance discrimination.

Massachusetts Division of Registration

100 Cambridge Street, 15th floor, Boston, MA 02202. Telephone: (617) 727-7046.

The Division of Registration is the umbrella organization for the Boards of Registration, which oversee licensed professions. The Division investigates complaints about discriminatory practices by doctors, dentists, nurses, and other medical providers.

Appendix XII

AIDS Information Lines in Massachusetts

AIDS Action Line 1-800-235-2331; (617) 536-7733 within the Boston Area Monday - Friday 9am - 9pm; Saturday 10am - 4pm; Sunday 12pm - 4pm

AIDS Hotline, City of Boston (617) 424-5916 Monday - Friday 8:30am - 4:30pm

AIDS Hotline
Somerville Portuguese-American League (SPAL)
1-800-232-SPAL
Monday - Saturday 9am - 5pm (recorded message after hours, Portuguese available)

Boston Alliance of Gay and Lesbian Youth (BAGLY) Hotline 1-800-42-BAGLY Available 24 hours

Latino AIDS Hotline Inquilinos Boricuas en Accion/Latino Health Network 1-800-637-3776; (617) 262-7248 within the Boston area Monday - Friday 12pm - 10pm (Spanish available)

Massachusetts Alcoholism and Drug Services Information and Referral Hotline Massachusetts Department of Public Health, Division of Substance Abuse 1-800-327-5050; (617) 445-1500 within the Boston area Available 24 hours

Massachusetts Alternative Test Site (ATS) Program
Massachusetts Department of Public Health
(617) 522-4090 (collect calls accepted)
Monday - Friday 8am - 6pm (Spanish, Portuguese, and French available)

Multilingual Helpline
International Institute of Greater Lawrence
(508) 688-HELP
Monday - Friday 8:30am - 4:30pm
(Spanish, French, Gujarati, Hindi, Khmer, Malayan, Tamil, Vietnamese available)

New North Citizens' Council Bilingual Hotline New North Citizens' Council 1-800-637-3776 Monday - Friday 9am - 5pm (Spanish available)

Operation Venus Information on Sexually Transmitted Diseases 1-800-272-2577 Monday - Friday 8am - 10pm

Quincy Health Department (617) 773-1380 x239 Monday - Friday 1pm - 4pm

Stanley Street Treatment and Resource Center, Fall River (508) 679-5222 x226 or x236 Monday - Friday 8:30am - 4:30pm (Spanish, Portuguese, and French available)

AIDS Information Lines in Massachusetts - continued

The Teen Line Department of Health and Hospitals, City of Boston (617) 424-5700 Monday - Friday 9am - 5pm

U.S. Public Health Service 1-800-342-AIDS Available 24 hours

Appendix XIII

Order Form for Clinical Trials Information

The Massachusetts Department of Public Health maintains a Clinical Trials Registry. The Registry publishes a directory of research studies for people affected by HIV and for their primary health care providers. The directory includes a statement of the purpose of each study, the requirements for concollment, and the names and phone numbers of physicians or nurses who can provide more detailed information. A key purpose of the directory is to make it easier for qualified patients to conticipate in clinical trials. The Clinical Trials Registry also publishes several informative pamphlets o acquaint patients and providers with the nature and purpose of clinical trials.
Check off the items you would like to receive. Where foreign language versions of the publication are available, please circle the language of your choice:
Massachusetts Cilnical Trials Directory for AIDS and HiV-Related Drugs
Clinical Trials: Information Related to AIDS and HiV infection An informative pamphlet for health care providers and the public.
Languages: English Spanish
3. An introduction to Clinical Trials A public education brochure.
Languages: English Spanish Portuguese Haitian Creole
4. AIDS Clinical Trials and Research: Considerations for Patients and Primary Care Providers A monograph for health care providers.
Name
Organization/Agency
Address
Telephone Date
Return this form to: Clinical Trials Information Series AIDS Office

Department of Public Health

150 Tremont Street Boston, MA 02111

Appendix XIV

Public Health Service Statement: Management of Occupational Exposure to HIV

Excerpts from MMWR Recommendations and Reports, *Public Health Service Statement on Management of Occupational Exposure to Human Immunodeficiency Virus, Including Considerations Regarding Zidovudine Postexposure Use,* January 26, 1990.

Considerations Regarding Use of Zidovudine After an Occupational Exposure

Risk of HiV infection after exposure

Evaluation of the risk of HIV infection after exposure should take into account existing knowledge from prospective studies of exposed workers, which demonstrate that on the average the risk of transmission of HIV per episode of percutaneous exposure (e.g., a needlestick or cut with a sharp object) to HIV-infected blood is approximately 0.4 percent. These studies also suggest that the risk of HIV transmission per episode of mucous-membrane or skin exposure to HIV-infected blood is less than that after a percutaneous exposure. The risk of HIV transmission after occupational exposure to body fluids other than blood, for which universal precautions are recommended, is unknown. The risk of HIV infection for persons who take zidovudine postexposure prophylaxis cannot be determined at present because of the small number of persons studied.

Risk evaluation should also include an assessment of factors that may increase or decrease the probability of HIV transmission after an individual occupational exposure. These factors are not well understood, but include the likelihood that the source fluid contained HIV and probably also the concentration of HIV in the source fluid, the route of exposure, and the volume of the fluid involved. For example, a percutaneous exposure to concentrated HIV in a research laboratory is probably more likely to result in transmission of infection than a similar exposure to HIV-infected blood in a clinical setting. A percutaneous exposure to HIV-infected blood is probably more likely to result in transmission than a mucous-membrane exposure to the same blood. Finally, an exposure to a larger quantity of HIV-infected blood, such as injection of several milliliters, is probably more likely to result in HIV transmission than an exposure to a smaller quantity of the same blood, such as in a needlestick exposure.

Data from animal and human studies are Inadequate to establish the efficacy or safety or zidovudine for prophylaxis after occupational exposure to HIV. However, some physicians believe that zidovudine should be offered as prophylaxis to persons after certain occupational exposures for the following reasons: the severity of the illness that may result from HIV infection, the documented antiviral effect of zidovudine in the treatment of persons with established HIV infection, the apparent reversibility of acute toxicity in persons taking zidovudine for a brief period, and the suggestion that in some animal studies, zidovudine postexposure may modify the course of some retroviral infections. Other physicians believe that zidovudine should not be recommended for uninfected persons after occupational exposures because of the lack of data demonstrating efficacy in postexposure prophylaxis, the limited data on toxicity in uninfected individuals, and the fact that zidovudine has been shown to be carcinogenic in rats and mice.

At this time prophylaxis with zidovudine cannot be considered a necessary component of postexposure management. However, workers who might be at risk of occupational exposure to HIV should be informed, as part of job orientation and ongoing job training, of the considerations pertaining to the use of zidovudine for postexposure prophylaxis.

interval between exposure and initiation of prophylaxis, if given

Data from animal studies suggest that prophylaxis against certain retroviral infections other than HIV may be more effective when started within hours after exposure. Because in vitro studies indicate that human HIV infection may be extablished in human lymphocytes within hours after exposure, and epidemiologic studies of exposed health-care workers indicate that acute retroviral illness may occur as early as two weeks after exposure, it appears that if the decision is made to use postexposure prophylaxis, prophylaxis should be initiated promptly.

Public Health Service Statement - continued

Counseling and Informed consent

If zidovudine prophylaxis is being considered, the worker should be counseled regarding a) the theoretical rationale for postexposure prophylaxis, b) the risk of occupationally acquired HIV infection due to the exposure, c) the limitations of current knowledge of the efficacy of zidovudine when used as postexposure prophylaxis, d) current knowledge of the toxicity of zidovudine (including the data from animal and human studies) and the limitations of this knowledge in predicting toxicity in uninfected individuals who take the drug after occupational exposures, and e) the need for postexposure follow-up (including HIV serologic testing), regardless of whether zidovudine is taken. The worker should also be informed that there are diverse opinions among physicians regarding the use of zidovudine for postexposure prohylaxis, and the Public Health Service cannot make a recommendation for or against the use of zidovudine for this purpose because of the limitations of current knowledge.

The duration of follow-up needed to detect evidence of HIV transmission or delayed toxicity among workers who take zidovudine is presently unknown. Workers taking zidovudine postexposure may require follow-up to detect HIV seroconversion for a longer period than that recommended for workers who do not take zidovudine. Regardless of the length of follow-up, mechanisms should be developed to permit workers taking zidovudine to be contacted if future information indicates the need for additional evaluation.

If a physician offers zidovudine as prophylaxis after an occupational exposure and the exposed worker elects to take the drug, the physician or other appropriate health-care provider should obtain written informed consent from the worker for this use of this drug. The consent document should reflect the information presented in the counseling session, as outlined above, emphasizing the need for follow-up medical evaluations and for precautions to prevent the transmission of HIV infection during the follow-up period, including refraining from blood, semen, or organ donation, refraining from breast-feeding, and either abstaining from sexual intercourse or using latex condoms during sexual intercourse.

Considerations regarding sexual intercourse for exposed workers taking zidovudine include 1) the possible risk of teratogenisis associated with zidovudine use, and 2) the risk of transmission of HIV to a sexual partner. The risk of teratogenesis among offspring of either men or women taking zidovudine is unknown. Therefore, men and women of reproductive age who are receiving zidovudine should abstain from, or use effective contraception during, sexual intercourse throughout the time zidovudine is being taken. In addition, to prevent HIV transmission to sexual partners, all exposed workers, including pregnant women, should abstain from, or use latex condoms during, sexual intercourse throughout the follow-up period.

Prophylaxis schedules currently used after occupational exposure

Various regimens have been prescribed for zidovudine prophylaxis after occupational exposure. No data are available to enable investigators to determine the efficacy or compare the toxicity of these or other regimens. At the National Institutes of Health Clinical Center, workers who elect to receive zidovudine are treated with 200 mg every 4 hours (five times daily; no dose is given at 4:00 a.m.) for 4 weeks. Some clinicians have used an initial dose of 400 mg, and others have prescribed treatment courses ranging from 4 days to 4 months. At several institutions, attempts are made to begin prophylaxis within 1 hour after exposure for workers who elect to receive the drug.

Public Health Service Statement - continued

Contacts for Physicians and Occupational Health Professionals

To enroll persons who have had a "massive exposure" to HIV in NIAID study of zidovudine prophylaxis, telephone 1-800-537-9978.

To report adverse effects associated with zidovudine to FDA, use "Adverse Reaction Report" forms (FDA #1639), obtainable from:

Food and Drug Administration Office of Epidemiology and Biostatistics HFD-730 Rockville, MD 20857 (301) 443-4580

To enroll pregnant women who receive zidovudine during pregnancy, contact:

Zidovudine in Pregnancy Registry
Epidemiology, Information, and Surveillance Division
Burroughs-Wellcome Company
3030 Cornwallis Road
Research Triangle Park, NC 27709
(919) 248-8465 (collect) or 1-800-722-9292

The Massachusetts Department of Public Health wishes to acknowledge the cooperation and assistance of the City of New York Department of Health in preparing these Guidelines.

Department of Public Health AIDS Office 150 Tremont Street Boston, Massachusetts 02111

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